HEARLab System

Operator's Manual

June 15, 2015

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Introducing the HEARLab System

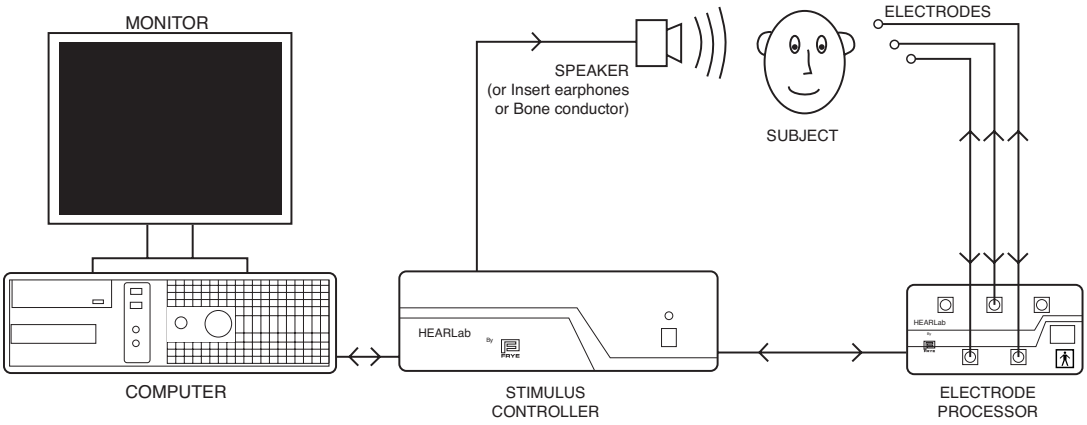
1.1 System Overview

Welcome to the HEARLab® System, manufactured by Frye Electronics, Inc. under license by the National Acoustics Laboratory (NAL) of Australia.

This manual describes the Aided Cortical Assessment (ACA) software module, which is intended to determine if a Cortical Auditory Evoked Potential (CAEP) is present in a patient wearing a hearing aid who is exposed to auditory signals in the low, mid and high frequency bands associated with normal hearing.

The HEARLab ACA module also contains the Cortical Tone Evaluation (CTE) sub-module. In the CTE mode a number of frequency specific tone bursts can be used to evaluate the audibility of specific frequencies at different levels.

The HEARLab system consists of a personal computer running the HEARLab ACA software module in the Microsoft Windows® environment, and a set of specialized but versatile hardware components. The hardware contains electronic circuits that can be configured and controlled by the software to deliver the correct acoustic stimulus and to acquire the evoked cortical response. The software performs the required signal processing, manages record keeping and interacts with the tester.



1.2 Intended Use

The HEARLab device is intended for use in evoking an auditory response and recording, analyzing, and displaying the resulting human electro-physiological data as an aid for hearing assessment used in conjunction with other clinical devices (such as an audiometer or an auditory brainstem response device).

Healthcare professionals trained in auditory evoked potentials can use HEARLab in order to determine whether the Cortical Auditory Evoked Potential (CAEP) is absent or present in humans from infants who are 42 weeks gestational through adults when stimulated with speech tokens presented in the sound field. This test can be performed on unaided subjects and subjects wearing hearing instruments. However, it is not meant to be used on subjects with cochlear implants.

HEARLab® is the registered trademark of HearWorks Pty Ltd. All rights reserved.

These professionals can also use HEARLab to determine audibility of unaided frequency specific tones presented to adults using CAEP. Only audiologists should use information acquired by HEARLab in diagnosing a hearing loss or in verifying the effectiveness of a hearing aid.

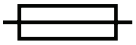
1.3 Safety and Precautions

1.3.1 Meaning of Symbols

These symbols are found on the Stimulus Controller.

Patient applied parts of HEARLab are type BF.

Read the accompanying documents. Please read this manual before operating HEARLab.



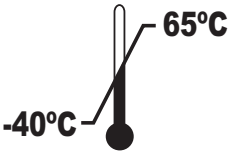
Replace fuses only with same type and rating (1A, 250V, Time LAG).

CE signifies compliance with the European Union's Medical Devices Directive 93/42/EEC.

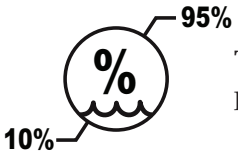
Shipping

The following symbols are included on the electronic module shipping box:

Keep dry. The HEARLab System should not be exposed to water or other fluids.



The shipping/storage temperature of the HEARLab System is -40 to 65 degrees Celsius (-40 to 149 degrees Fahrenheit)



The shipping/storage Humidity of the HEARLab System is 10 to 95 percent relative humidity (non-condensing)

1.3.2 Reporting/Factory Location

If you are located in the European Union, please report all safety-related concerns to our authorized representative:

Sivantos Ltd.
Platinum House
Sussex Manor Business Park
Gatwick Road
Crawley RH10 9NH
ENGLAND

Otherwise, please report all safety-related concerns to the Frye factory:

Frye Electronics, Inc.
9826 SW Tigard St
Tigard OR 97223
Phone: 503-620-2722, 800-547-8209
Fax: 503-639-0128
Email: support@frye.com (operational help), sales@frye.com (sales/price questions), service@frye.com (malfunctioning equipment)

Frye Electronics, Inc. is a Registered Firm of British Standards Institution, and we conform to the ISO 13485 standard.

1.3.3 Safety Classification

The HEARLab system complies with:

- IEC 60601-1 and AS/NZS3200.1.0 Medical electrical equipment - Part 1.0: General requirements for basic safety and essential performance.
- IEC 60601-1-2, collateral standard for Electromagnetic compatibility requirements (See Section 1.3.4 for more details.)
- Australian Therapeutic Goods Administration, Class 1 (Rule 4.1)
- European Medical Device Directive, Class 11a (Rule 10)
- U.S. FDA, Class 2
- ISO 13485: 2003

Safety Classification for IEC 60601-1

Type of protection against electrical shock: Class 1

Degree of protection against electrical shock: Type BF

Mode of operation: Continuous

Degree of protection against the ingress of water: Ordinary

The HEARLab System does not require sterilization.

Warning: The HEARLab System is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The HEARLab ACA software is indicated for use in the recording and analysis of human electro-physiological data as an aid in the assessment of hearing and hearing-related functions. The data is obtained with electrodes attached to the scalp of the subject to detect the presence or absence of electro-physiological signals that may be evoked in response to auditory stimulus. These electro-physiological signals being monitored are not intended to indicate signals vital to life or health or state of well being of the patient.

Note that for conformance to IEC 60601-1 Type BF patient isolation requirements the HEARLab System must be setup in accordance with instructions in Section 2.4.

It should be noted that it is the user's responsibility to ensure that conformance to IEC 60601-1 Type BF patient isolation requirements are maintained when patient-connected equipment or accessories not supplied by Frye Electronics are used with or in conjunction with the HEARLab System.

1.3.4 Electromagnetic Compatibility

The HEARLab System acquires and analyses signals of low amplitudes with circuits that that are sensitive to electrical interference. Some forms of electrical interference may cause interruption of the cortical measurement tests. For further information, see Appendix C for notes that may be helpful in identifying and resolving sources of interference.

HEARLab complies with IEC 60601-1-2 with the following deviations:

36.202.2 Electrostatic discharge (ESD): The HEARLab Cortical Analyzer is sensitive to high voltage discharges. However, the analyzer software monitors measurements for electrical noise that exceed the dynamic range of the system, including that which may result from this type of discharge, and discards it from final test results. Furthermore, no adverse harm comes to the patient from the application of these discharges.

36.202.3 Radiated RF electromagnetic fields: While testing at 3 V/m, between 80 MHz and 700 MHz, the EEG and most recent epoch graph will show invalid measurement data. If this electrical noise exceeds the dynamic range of the system, it will be automatically blocked from final test results. If this noise is within the dynamic range of the system, it will be included in test results, but should be averaged out if the noise is short in duration.

36.202.4 Electrical fast transients and bursts: Power fluctuations may cause the Cortical Analyzer software to close. This will lead to the loss of data for any running test, but will not affect saved test results or the safety of the user or patient. To prevent this occurrence, it is recommended to use a surge protector or uninterruptible power supply (UPS power backup).

36.202.6 Conducted disturbances, induced by RF fields: While testing at 3 Vrms, the EEG and most recent epoch graphs will include noise and may result in a moderate to loud tone from the speaker. In most cases, this noise will exceed the dynamic range of the system and will be automatically discarded and excluded from final test results. Noise that does not exceed the dynamic range of the system may be included in test results, but will be averaged out of long term results as long as the signal is short in duration. Any tone(s) issuing from the loudspeaker that is not synchronous with the computer driven stimulus is ignored by the averaging system and will not affect test results.

1.3.5 Warnings

This section contains important safety warnings. Please read carefully before operating the HEARLab ACA software.

The HEARLab System should only be used for purposes described in this operator's manual.

Warning: The HEARLab System is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Warning: Be aware that some patient populations may be at particular risk for injuries related to excessive scrubbing of the skin prior to electrode placement (e.g., burns patients, premature infants). If in any doubt, seek medical advice.

Warning: Do not use undue physical force when preparing skin or applying electrodes. Take particular care when applying electrodes to infants, particularly the vertex electrode, where the fontanel area is susceptible to injury.

1.3.6 Cautions

This section contains important safety precautions. Please read carefully before operating the HEARLab ACA software.

Several studies have shown that some patients do not exhibit a strong CAEP even when the stimulus is far above their behavioural threshold. Therefore, the absence of a cortical response should not be used as a definite diagnosis for a hearing loss, and further auditory testing is recommended.

The Cortical Tone Evaluation (CTE) test has been validated for the use of adults only. This test has not yet been validated for the use in testing infants or children.

Federal law restricts this device to sale by or on the order of a licensed hearing health professional.

Keep water away from the HEARLab System and its electronic accessories. Spilling water on the device or immersing the electrodes in water, for example, will be considered customer damage and will void the warranty.

Acoustical Levels and Patient Safety:

The software and hardware are designed to limit the acoustical signal to levels that are not harmful to a patient, even if a malfunction should occur. Malfunction of the device, including the software, may result in uncomfortably loud levels but is unlikely to cause even minor injury to the patient.

Acoustically evoked electro-physiological signals are picked up by passive electrodes placed on the scalp of the subject. Malfunction of the device, including the software, is unlikely to cause minor injury or discomfort to the patient.

Setup and Connections:

To avoid electric shock hazard, care must be taken to connect cables and accessories in exact accordance with the user instructions. Only appropriately trained and skilled personnel should attempt to install the HEARLab System.

The HEARLab System should be used in a clinical test environment with low ambient noise and electromagnetic field levels. Unsuitable test environments could lead to bad test results.

Safe use of the HEARLab System may be compromised if the user connects unsuitable equipment to the Stimulus Controller Unit.

Use only the electrode cables supplied with the HEARLab System. Do not attempt to substitute any other cables. The use of alternate electrode cables could lead to bad test results.

Avoid the use of extension cables, or placing power cables where they present a tripping hazard. Keep hardware and cables out of children's reach.

Keep the HEARLab System hardware isolated in a well-ventilated area. It should not be operated in a tightly enclosed area or stacked with other electrical equipment. Failure to do so could overheat the equipment and lead to failure.

All electrical equipment within the patient test area should have approved medical safety status. Failure to follow these instructions could lead to interference with nearby medical equipment.

Electrode application and removal:

Electrodes must be applied by suitably qualified and experienced personnel. Universal precautions should be applied to reduce the risk of patient infection.

Avoid contact with broken skin, or patients with existing skin conditions. Electrode contact in these circumstances could further damage the skin.

Substances used to prepare electrode sites (e.g., abrasive liquids, gel, cream or paste), or to adhere electrodes to the skin (e.g., self adhesive electrodes, medical tapes), or the electrode itself, may produce allergic or other dermatologic reaction in some individuals. Check for history of allergic reactions before preparing electrode sites/applying electrodes.

Substances used for electrode preparation and placement should be selected with regard to the manufacturer's recommendations for use with patients. Always read and follow the manufacturer's written instructions. Avoid contact with the patient's eyes. Alcohol preparation swabs are not recommended for use on infants.

Clinicians who have skin sensitivities should also avoid prolonged contact with preparation substances or consider wearing gloves during electrode preparation application and removal.

Dispense preparation substances in a hygienic manner using single-use, disposable applicators (e.g., cotton swabs). To reduce the risk of discomfort or infection, avoid aggressive abrading of the skin when preparing electrode sites. Avoid the use of dry abrasive pads.

Thoroughly clean the skin immediately after electrode removal using clean water. Harsh agents (e.g., alcohol, acetone) are not recommended.

1.3.7 Interpretation of Results

The HEARLab ACA software is intended to be user-friendly and simple to use. However, the system should only be used for electrophysiological assessment and only by personnel with appropriate training and experience.

Results may be invalid if:

- The calibration procedures are not correctly followed prior to testing (Section 3.6)
- Transducers (e.g., insert earphones) are changed and the system is not recalibrated prior to use (Section 3.9)
- Electrode contact is poor (> 5 kΩ) (Section 3.4.4)
- Excessive electromagnetic interference is present in the test environment
- The patient is drowsy or asleep.
- The patient is restless and/or overheated.
- Insufficient quality (noise-free) cortical recordings are obtained.

Caution: Several studies have shown that some patients do not exhibit a strong CAEP even when the stimulus is far above their behavioural threshold. Therefore, the absence

of a cortical response should not be used as a definite diagnosis for a hearing loss, and further auditory testing is recommended.

Caution is recommended when evaluating CAEP results in infants. For speech sounds exceeding 10 dB Sensation Level, 23% of evoked corticals are NOT present / detected (false negative). This means that any audiological decisions should not be made based on cortical measurements alone!

There is also a 5% false positive expected in ACA measurements.

1.4 Maintenance

This section describing servicing, cleaning and disposal of the HEARLab Cortical Analyzer.

1.4.1 Service

The HEARLab System hardware must only be repaired or serviced by a qualified technician. There are no user serviceable parts inside the Stimulus Controller or the Electrode Processor. Do not attempt to open the external casings of these components.

Calibration should be performed at least once a year in accordance with the procedures described in Section 3.9.

1.4.2 Cleaning

The Stimulus Controller and the Electrode Processor may be wiped with a dry cloth. Do not allow liquids to come into contact with the HEARLab System hardware.

Single-use, disposable sensor pads are used with the HEARLab electrode connector system. Refer to the manufacturer's information to ensure appropriate use. To avoid the possibility of cross-infection, do not attempt to clean or re-use disposable sensor pads.

When insert earphones are used as stimulus generators, do not reuse the insert earphone eartips. Sterilization of these eartips is not possible. When performing these measurements, make sure to use a new tip for each patient.

1.4.3 Disposal of Equipment

The HEARLab System and some of its accessories contain lead. When the user has decided that the HEARLab equipment is not longer serving its intended purpose and is to be discarded, the HEARLab devices should be disposed of in accordance with local waste disposal regulations. Consult the local waste disposal authority on the relevant regulations applicable.

1.5 Warranty

The HEARLab System and all accessories except the electrodes are guaranteed to be free of manufacturing defects that would prevent the product from meeting its specifications (given in Appendix D of this manual) for a period of one year from the date of purchase when the following conditions are met:

- The cases of the Stimulus Controller and the Electrode Processor have only been opened for modification or repair by persons authorized by Frye Electronics or one of its official distributors.

- The installation of the HEARLab System complies with relevant requirements.
- No additional software has been installed on the personal computer supplied with the device.
- All components connected to the HEARLab System have been provided by Frye Electronics.

The electrodes have a limited three-month warranty covering manufacturing defects only. This warranty does not extend to cover customer damage.

The HEARLab Hardware

This chapter describes the HEARLab hardware components and how to set them up for testing.

2.1 Main Hardware Components

Personal Computer

The HEARLab System is built around a standard PC operating under Windows XP Professional. The HEARLab ACA softare is installed at the factory. The computer includes the following components:

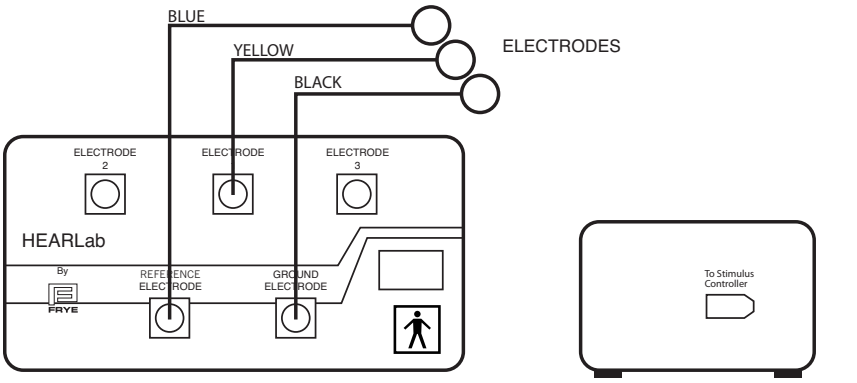
The PC is connected to the Stimulus Controller with a USB cable.

Stimulus Controller

The Stimulus Controller (SC) is the HEARLab System's main hardware unit. It connects directly to the PC with a USB cable and functions as an Input/ Output device that connects to various transducers. A power cable for the SC module is also included.

Electrode Processor

The Electrode Processor (EP) is a small box that is used for connecting the electrodes. It is connected to the jack on the Stimulus Controller labeled "To Electrode Processor". This device provides electrical isolation between the electrodes and the cable connected to the stimulus controller.



ELECTRODE PROCESSOR (top panel) ELECTRODE PROCESSOR (side panel)

Electrodes

Consist of custom set of cables that incorporate amplification at the electrode connector snaps. The recommended sensor pads (Blue Sensor) are single use and commercially available.

Three electrodes are included with HEARLab ACA. A ground electrode with a black connector (p/n: GNDELEC), a reference electrode with a blue connector (p/n: REFELEC), and an active electrode with a yellow connector (p/n: ACTELEC). The electrodes connect to the Electrode Processor.

Electrode Sensor Pads

A package of 50 Ambu Blue Sensors (p/n: 026-0020-00) are included with the HEARLab System. The disposable electrode sensors have a limited shelf life and become less effective after the packaging has been opened. It is recommended to note the date a package of electrode sensors was opened and to dispose of any left over sensors a month after this date. If the HEARLab is not in frequent use, left over electrode pads in the formerly sealed electrode sack can quickly dry out and become unusable. It is recommended that between uses, unused pads be stored in a small, sealed, air tight pouch.

Control Microphone

This microphone is used for the calibration of the sound field during ACA measurements. (p/n: CONTROLMIC) It is connected to the jack labeled "Control Microphone" on the Stimulus Controller.

Free Field Loudspeaker

This free-standing speaker is used for performing ACA measurements. (p/n: 034-1261-00) It is meant to be placed in front of the patient on a table or other flat surface. A cable (p/n: 072-0262-00) is included to connect it to the jack labeled "Speaker Left" on the Stimulus Controller. An adapter is provided (p/n: 044-0047-00) for connecting to the speaker.

Insert Earphones

A pair of ER3A earphones for performing CTE measurements. (p/n: 015-0416-00) An assortment of disposable eartips is also included. The insert earphones use the "Insert Right" and "Insert Left" jacks on the back of the Stimulus Controller.

Bone Conductor

A Radioear B-71 bone conductor for perfoming CTE measurements. (p/n: 015-1224-00) It is connected to the “Bone” connector on the back of the Stimulus Controller.

SC/EP Cable

This “firewire” cable is used to connect the Stimulus Controller and the Electrode Processor. (p/n: 072-0312-00)

USB Cable

This cable is used to connect the Stimulus Controller to the Personal Computer. The square connector connects to the back of the Stimulus Contoller. The rectangular connector connects to the computer. (p/n: 072-0313-00)

2.2 Optional Accessories

Monitor Speaker

This is a second loudspeaker for use in a two-room setup. (p/n: 034-1261-00) It is placed in the control room and outputs sounds picked up by the control microphone. It requires a cable (p/n: 072-0262-00) and an adapter (p/n: 044-0047-00).

Speaker Floor Stand

This is a speaker plus the necessary mounting hardware and a floor stand. (p/n ACC/STAND/HEARLAB)

Note: The speaker that is normally included with HEARLab does not have the mounting hardware necessary to connect it to this floor stand.

Kid Pack

The Kid Pack (p/n KIDPACK PKG) is a selection of silent toys that are used to entertain babies and young children during the cortical test. Colors and shapes may vary, but the Kid Pack includes:
1 drawstring bag (p/n MESH BAG), 1 Oball Jelly (p/n OBALL), 1 Plushy (p/n PLUSHY), 1 Hand Puppet (p/n PUPPET), 3 headbands (P/N HEADBAND PKG), 1 container of bubbles (p/n BUBBLES).

2.3 System connections

2.3.1 Stimulus Controller Connections

The following connectors with function labels are available on the back of the Stimulus Controller. For the most part, connectors located in the upper row are outputs. Connectors in the bottom row are inputs.

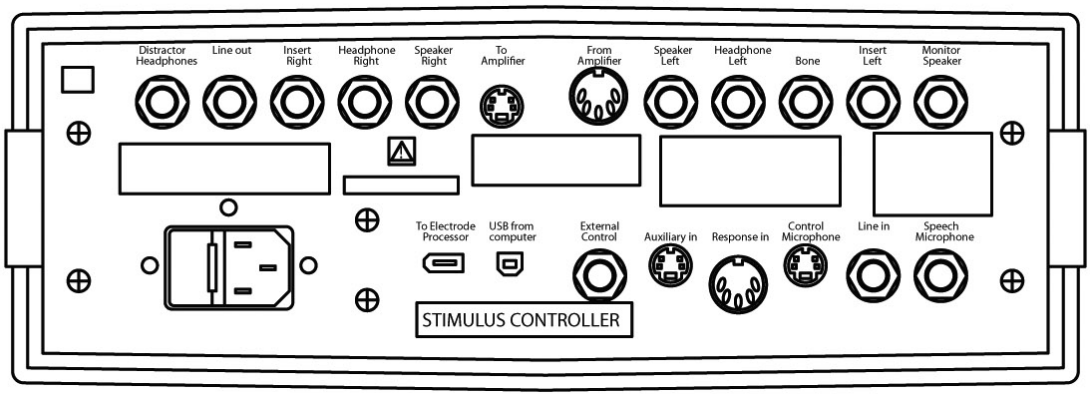


Figure 2.3.1: Stimulus Controller connectors

Upper Row

Distracter Headphones	(Not used in HEARLab ACA software)
Line Out	(Not used in HEARLab ACA software)
Insert Right	Right ER3A insert earphone
Headphone Right	(Not used in HEARLab ACA software)
Speaker Right	(Not used in HEARLab ACA software)
To Amplifier	Connects left and right stimulus signals to the input of an external amplifier **Caution**: Do not use any of the other jacks to connect the input of an external amplifier to the HEARLab System!
From Amplifier	Left and right speaker drive power from an external amplifier
Speaker Left	Left sound field speaker. **This is the speaker drive jack used for ACA stimulus presentations.**

Headphone Left	(Not used in HEARLab ACA software)
Bone	B71 Bone vibrator headset
Insert Left	Left ER3A insert earphone
Monitor Speaker	Speaker that monitors the stimulus and sounds in the test area. Input is from the control microphone.

Lower Row

Power connector/ fuse	Use a type 3AG size fuse, 1/2 amp, slow blow. Connect the HEARLab System to power line, 100 to 240 VAC, 50 to 60 Hz.
To Electrode Processor	Connection for Electrode Processor box
USB from Computer	USB connection to personal computer
External Control	(Not used in HEARLab ACA software)
Auxiliary In	(Not used in HEARLab ACA software)
Response In	(Not used in HEARLab ACA software)
Control Microphone	Control (reference) microphone used for calibration
Line In	(Not used in HEARLab ACA software)
Speech Microphone	(Not used in HEARLab ACA software)

2.3.1.1 USB stimulus controller connection to computer

The Windows 7 operating system has been found to have some interesting features that make the following action necessary:

When connecting the USB cable between the Stimulus controller and the computer, be sure to only plug the cable into the computer connector marked with the label ‘HEARLab’. The other end connects to the stimulus controller USB connector marked ‘USB from Computer’.

2.3.2 Electrode processor connections

The electrode processor provides electrical isolation between the set of electrodes, which are electrically connected to the patient, and the stimulus controller, which is connected to the ground and the electrical power mains. It also provides five sockets, three of which are used for the ACA and CTE test. The two additional sockets are planned for future electrode expansion use.

The three electrode connectors are color coded blue, yellow and black, for the reference, active and ground electrodes, respectively. Matching colors are used to indicate the positions of each of the three electrodes to be plugged into the electrode processor. The active and reference electrode connectors each contain active preamplifier circuits to help reduce pickup of external electrical interference. The cortical signals picked up and amplified by the electrodes are in the order of microvolts.

The electrodes are not designed to be discarded after use.

The miniature connectors used with the electrodes are designed to only fit the jacks provided on the electrode processor box, preventing accidental connection to undesirable sources of power.

The active ends of the electrodes are designed to be snapped onto foam pads that are normally discarded after a single use.

The electrode processor is connected to the stimulus controller through a special "firewire" cable. The processor is fitted with a cable restraint to remove unwanted strain on the processor connector. See figure 2.3.2. The two firewire connectors on each end of the cable are identical.

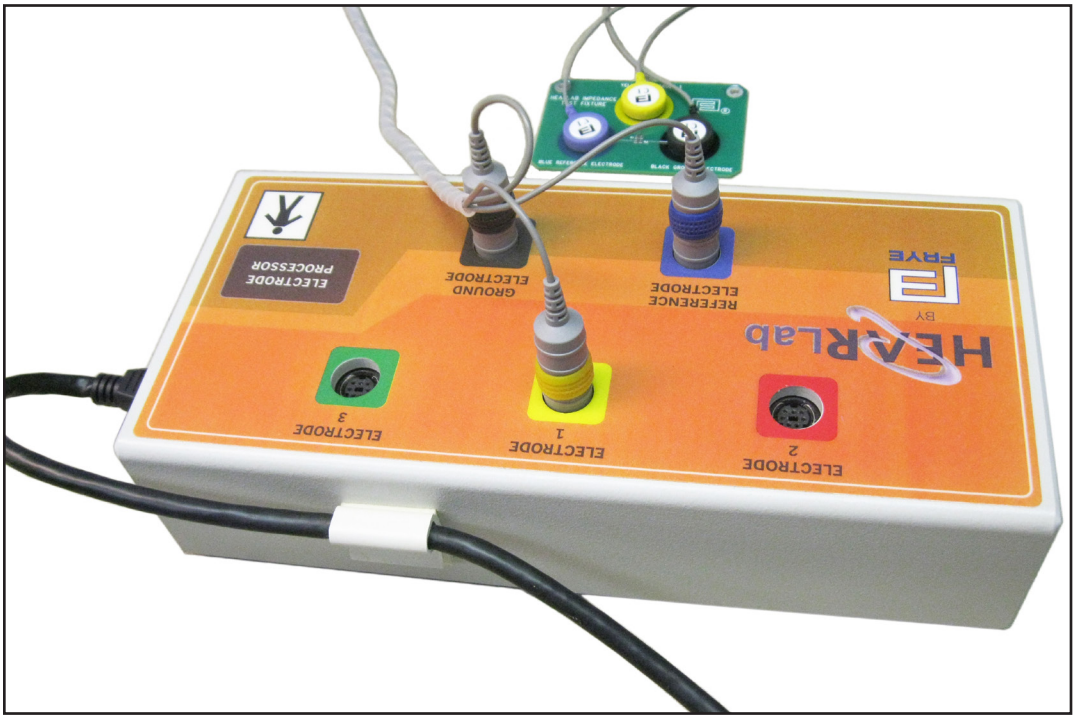


Figure 2.3.2: The electrode processor is connected to the stimulus controller through a special "firewire" cable.

Note: The active electrode connectors are not designed to be emerged in salt water or other fluid.

2.4 Installation

2.4.1 Site considerations

When choosing a site for the HEARLab System setup, take into account the site's ambient noise levels and potential sources of electro-magnetic interference. See Section 6 and Appendix B for more information on Ambient Noise Levels and how to measure them. When performing CTE measurements, a sound treated room is required. When performing ACA measurements, a quiet room may be sufficient.

HEARLab ACA and CTE measurements are designed to operate within the following ranges:

Temperature: 10-35° C
Relative humidity: 20-85% (non-condensing)
An air conditioned environment is recommended. On initial installation, allow 7 hours for the system to stabilize in the operating environment for reliable operation.

Cortical measurements are susceptible to electro-magnetic interference. See Appendix C for details.

2.4.2 Physical layout of system components

The device generally may operate in one or the other of the following physical configurations:

1. One-Room Setup: Subject and clinician are in the same room during measurements (Figure 2.4.2A).
2. Two-Room Setup: Clinician and Subject are located in separate environments such as a sound treated test booth and adjacent control room (Figure 2.4.2B).

One-Room Setup

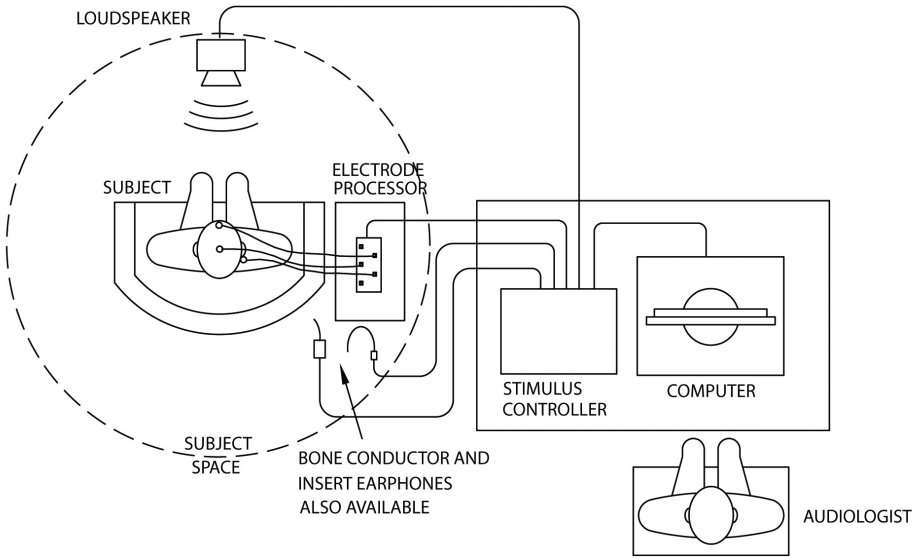


Figure 2.4.2A: HEARLab ACA One Room Setup

- Ideally an area is provided that maintains a distance of 1.5 meters between the patient and any electrically unknown object. Adhering to this distance will make it impossible or remote that the subject may be in contact with any object or equipment that is not electrically isolated to a medical level.
- Allow space for an assistant, often the infant's parent, who may present objects to the patient that attract attention. The objects should be presented in the general direction where the loudspeaker is located, so as not turn the subject's head away from the loudspeaker.
- A TV showing a silent movie can be used as a distracter to attract the patient's attention.

- Orient the PC's display away from the subject so that it is not visible.
- Arrange the setup so that the audiologist or tester is able to visually monitor the condition of the subject and the computer display
- The patient's chair or sofa should be comfortable to allow the subject to be relaxed.
- Include installation of the control microphone. See separate diagram.

Two-Room Setup

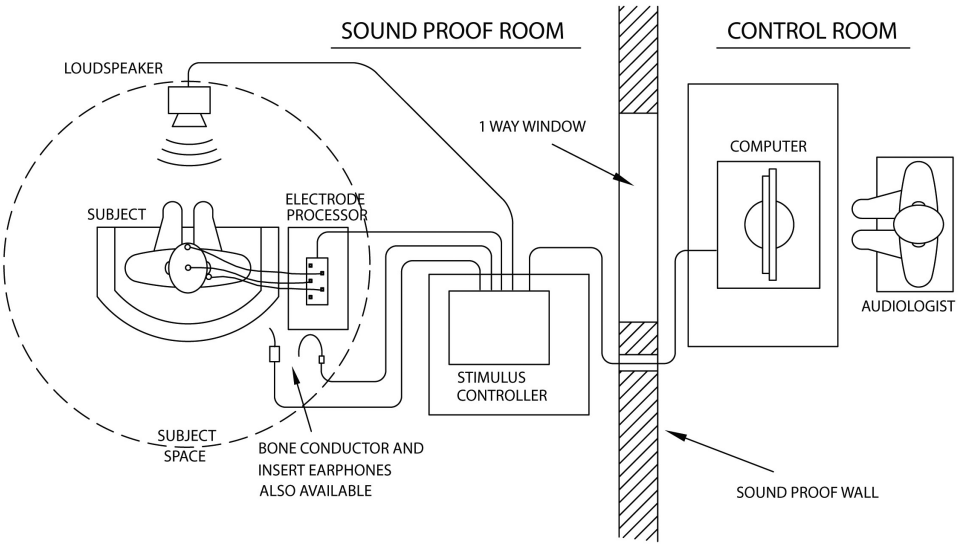


Figure 2.4.2B: HEARLab ACA Two-Room Setup

The basic requirements described above for the one room setup apply. In addition, consider the following points:

External power amplifier

If the distance between the loudspeaker and the nominal subject's head position is going to be more than 1.2 meters (4 feet), an external power amplifier driving a higher power loudspeaker may be required.

- Two sockets located at the back of the Stimulus Controller labeled "To Amplifier" and "From Amplifier" is provided to facilitate such a setup.
- See the Maintenance Manual for more information on using a two-room setup, including a diagram of the amplifier sockets.

Monitor loudspeaker

For 2 room setup, a monitor loudspeaker may be employed to allow the tester in the control/observation room to acoustically monitor the test space, including the acoustic stimulus, subject and distracter's voices.

- The socket labeled "Monitor Speaker" at the back of the Stimulus Controller is provided for cabling.
- The software allows the tester to adjust the volume of the monitor speaker to suit.

Note: The Electrode Processor handles very small signals in the microvolt range. Be sure to place this component on a surface free from electrical devices that can radiate electrical energy, including the top surface of the Stimulus Controller.

2.4.3 Connecting the system components

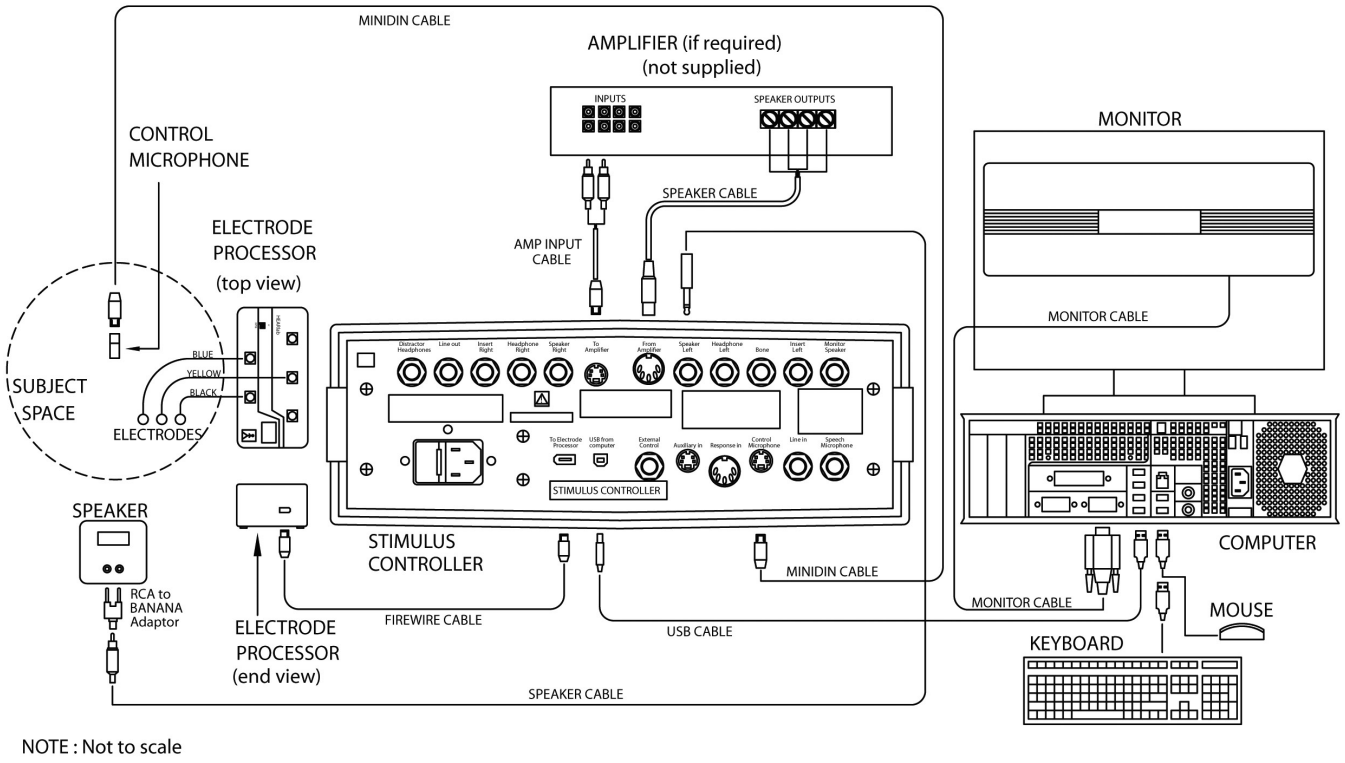


Figure 2.4.3: Connecting the system components

2.5 Start-up

To turn on HEARLab, locate the POWER on/off switch at the front of the SC. Power should be applied before attempting to start the ACA program. Once the power is on, the LED's on both the SC and EP will light up green, and there will be an audible 'click' as the hardware is initialised. After approximately 10 seconds, the ACA program on the computer can be started. It is recommended that the electrode cables be connected to the EP correctly and the electrode connectors are attached to the resistor pads before the hardware system is powered up.

If you attempt to start ACA before powering on HEARLab, you will be advised with an on-screen message to indicate that only results viewing will be allowed. If you want to conduct an assessment, you will need to exit and restart the software application.

Do not install or run any other software programs on the computer that is used for HEARLab.

2.6 Calibration

The insert earphones and bone conductor are calibrated at the factory prior of shipment. The calibration procedure is described in the HEARLab Maintenance Manual which can be referenced for more information.

The user is responsible for calibrating the free field loudspeaker used during ACA testing. The procedure is described in Chapter 4.

2.7 Summary Specifications

Tests Available

ACA	Aided Cortical Assessment (ACA)
	Cortical Tone Evaluation (CTE)

Input Channels

Stimulus Controller	2 Microphone channels
Electrode Processor	2-Channel recording (the cortical response signal and the stimulus signal)

Output Connections

Stimulus Controller	Free field loudspeaker (test loudspeaker)
	Free field loudspeaker (monitor loudspeaker)
	Insert earphone, left and right
	Bone conductor

Stimuli and Levels

ACA Stimuli	Speech sounds /m/, /t/, /g/, /s/
ACA Output and Levels	Free field output only @ 55, 65 and 75 dB SPL*
CTE Stimuli	Pure tones 500, 1k, 1k5, 2k, 3k, 4k Hz
CTE Output and Level	Insert phones: -10 — 110 dB HL, 5 dB steps
	Bone conductor: -10 — 70 dB HL, 5 dB steps (60 dB HL for 500 Hz)

Masking Signals

CTE:	Narrow-band noise

See the HEARLab Maintenance Manual for more detailed technical specifications.

WARNINGS

The HEARLab System is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Be aware that some patient populations may be at particular risk for injuries related to excessive scrubbing of the skin prior to electrode placement (e.g., burns patients, premature infants). If in any doubt, seek medical advice.

Do not use undue physical force when preparing skin or applying electrodes. Take particular care when applying electrodes to infants, particularly the vertex electrode, where the fontanel area is susceptible to injury.

CAUTIONS

Several studies have shown that some patients do not exhibit a strong CAEP even when the stimulus is far above their behavioural threshold. Therefore, the absence of a cortical response should not be used as a definite diagnosis for a hearing loss, and further auditory testing is recommended.

Electrodes must be applied by suitably qualified and experienced personnel. Universal precautions should be applied to reduce the risk of patient infection.

Avoid contact with broken skin, or patients with existing skin conditions. Contact with electrodes could further damage the skin.

Substances used to prepare electrode sites (e.g., abrasive liquids, gel, cream or paste), or to adhere electrodes to the skin (e.g., self adhesive electrodes, medical tapes), or the electrode itself, may produce allergic or other dermatologic reaction in some individuals. Check for history of allergic reactions before preparing electrode sites/applying electrodes.

Substances used for electrode preparation and placement should be selected with regard to the manufacturer's recommendations for use with patients. Always read and follow the manufacturer's written instructions. Avoid contact with the patient's eyes. Alcohol preparation swabs are not recommended for use on infants.

Clinicians who have skin sensitivities should also avoid prolonged contact with preparation substances or consider wearing gloves during electrode preparation application and removal.

Dispense preparation substances in a hygienic manner using single use, disposable applicators (e.g., cotton swabs). To reduce the risk of discomfort or infection, avoid aggressive abrading of the skin when preparing electrode sites. Avoid the use of dry abrasive pads.

Thoroughly clean the skin immediately after electrode removal using clean water. Harsh agents (e.g., alcohol, acetone) are not recommended.

Federal law restricts this device to sale by or on the order of a licensed hearing health professional.

HEARLab ACA Measurements

ACA is the first ERA test module in the HEARLab test suite. Two test protocols are provided in ACA: Aided Cortical Assessment (ACA) and Cortical Tone Evaluation (CTE).

Only audiologists should use HEARLab to acquire information to be used in diagnosing a hearing loss or in verifying the effectiveness of a hearing aid.

Caution: Several studies have shown that some patients do not exhibit a strong CAEP even when the stimulus is far above their behavioural threshold. Therefore, the absence of a cortical response should not be used as a definite diagnosis for a hearing loss, and further auditory testing is recommended.

Caution is recommended when evaluating CAEP results in infants. For speech sounds exceeding 10 dB Sensation Level, 23% of evoked corticals are NOT present / detected (false negative). This means that any audiological decisions should not be made based on cortical measurements alone!

There is also a 5% false positive expected in ACA measurements.

Aided Cortical Assessment

ACA involves presenting speech sounds at conversational levels to an aided or unaided client via free field, and measuring the evoked cortical response. This is particularly useful for testing infants or young children who have been fitted with hearing aids and are too young to have behavioral threshold testing performed.

Three speech sounds (/m/, /t/ and /g/), representing speech in the low, mid, and high frequency respectively, are available for choice, and they can be presented at 55, 65 or 75 dB SPL. An additional speech sound (/s/) has been added to assist in the determination of proper operation of a frequency transposition program present in some hearing aids.

Cortical Tone Evaluation

CTE involves presenting tonal stimuli to an unaided client via insert phones or bone conductors, and measures the evoked cortical responses to determine the audibility of highly-frequency specific tones.

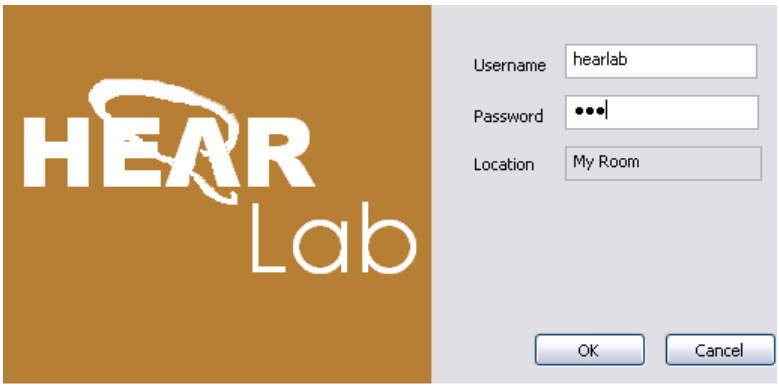
Six tonal stimuli (500 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz and 4 kHz) are available for testing. Levels from 0 dB HL – 110 dB HL can be presented through insert phones, and levels from 0 dB HL – 70 dB HL can be presented through bone conductors. Masking signal (narrow-band noise) can also be applied where appropriate at levels -30 dB – 10 dB relative to stimulus level.

3.1 Starting up

To power up the HEARLab System and turn on the HEARLab ACA software:

1. Turn on HEARLab using the POWER switch on the Stimulus Controller (SC).

2. Double-click the ACA icon.
3. A log-in window will appear.
4. Type your assigned username and password, then click **OK** or hit ENTER to proceed.



The Login window

3.2 Working with Clients

The Client window is the first window displayed when the HEARLab ACA program is opened. See "Figure 3.2" on page 22.

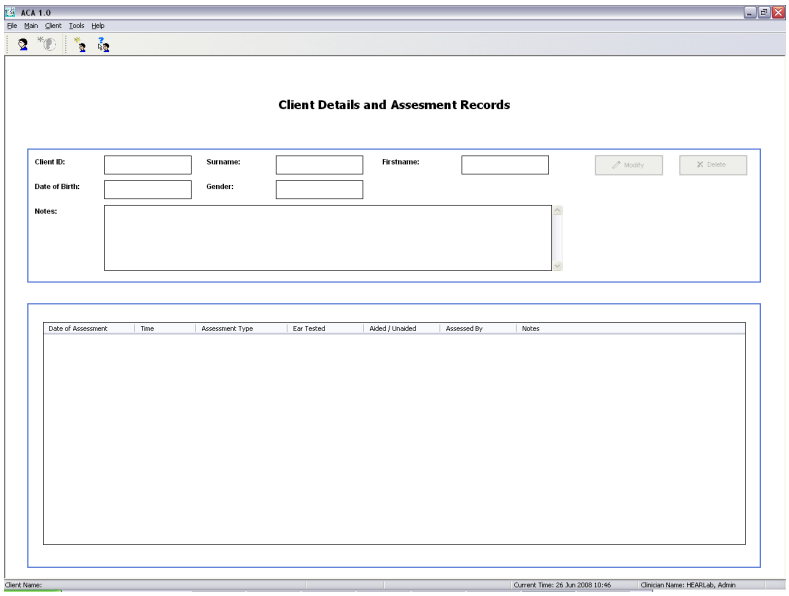


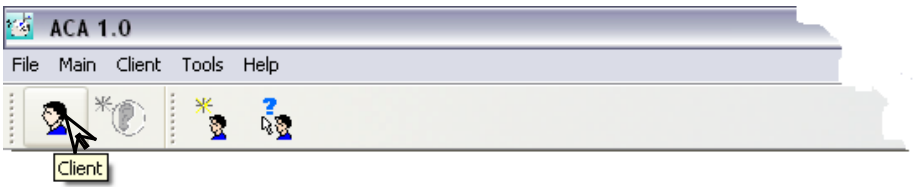
Figure 3.2: Client window

When you are in the Client window, you can:

- Add a new client record or open an existing client record
- Modify client's details or delete a client record
- Open a client's assessment results
- Delete client assessments

To access the Client window at other times:

- Click the **Client** button on the main toolbar, or

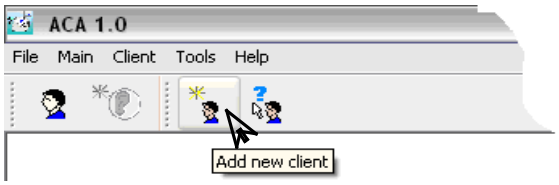


- Open the **Main** menu and select **Client**.

Note: It is necessary to select a client before you can proceed to a new assessment

3.2.1 Adding a new client

1. Open the Add New Client window (see “Figure 3.2.1” on page 23).
   - Click the **Add New Client** button on the toolbar, or



   - Open the **Client** menu and select **Add New...**

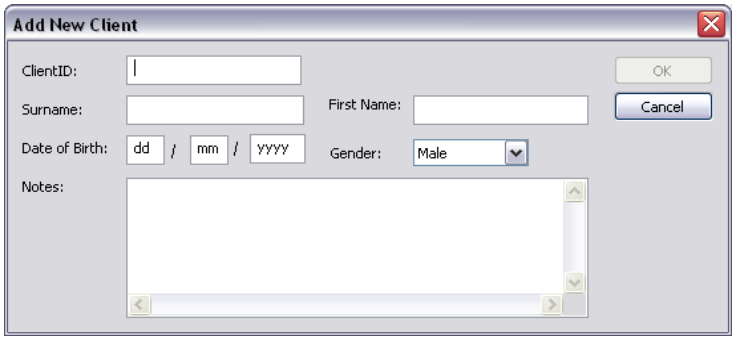


Figure 3.2.1: The Add New Client window

2. Input the following client details:
   - ClientID – this is the unique reference number for each client. You can enter a maximum of 10 digits
   - Surname
   - First name
   - Date of birth (dd/mm/yyyy)
   - Gender
   - Notes – any additional comments you may wish to make about the client. You may type up to 500 characters.
3. Click **OK** to save the new client record to the database. The newly added client record will be automatically selected.

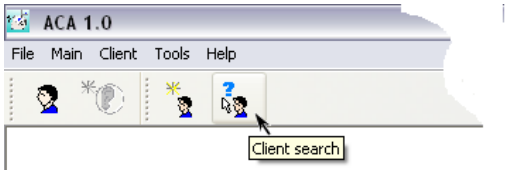
3.2.2 Working with an existing client record

To open an existing client record, you can:

- Search for the client using client details, OR
- Find the client after listing all the clients in the database

3.2.2.1 Searching for a client record

1. Open the Client Search window (See Figure 3.2.2A).
   - Click the **Client Search** button on the toolbar, or



   - Open the **Client** menu and select **Search for Client.**

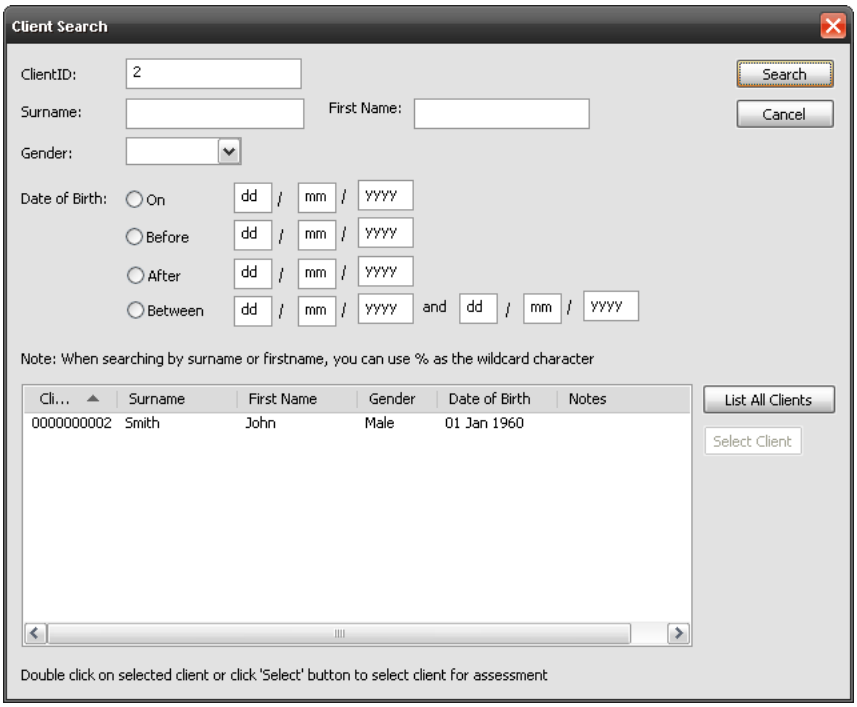


Figure 3.2.2A: The Client Search window

2. Type the details you want to use for your search. This can be:
   - Exact ClientID
   - Exact surname or partial surname with the wildcard character % (for example, use 'Smi%' to search for all clients with a surname starting with S-m-i)
   - Exact first name or partial name with the wildcard character '%'
   - Exact date of birth (DOB) or date range:

  - Before a certain date
  - After a certain date
  - Between two certain dates
- Gender
- Combination of client details. (*Note:* ClientID takes precedence over all other fields. If you put in a ClientID as well as other details, the search will be performed on the ClientID only.)

3. Click **Search** or press ENTER. A list of matching records or a "No client found" message will appear.

3.2.2.2 Listing all existing clients

1. Open the Client Search window (Figure 3.2.2A):
   - Click the **Client Search** button on the toolbar, or
   - Open the **Client** menu and select **Search for Client.**
2. Click the **List All Clients** button in the Client Search window. This will display all existing client records in the database.

3.2.2.3 Selecting a client record

Once you have located the client record (by either searching for the client by using search criteria, or finding the client in the list of all existing clients), open it by either double-clicking it, or single-clicking on it and clicking **Select Client**.

The selected client details, along with a list of the client's previous assessment records, will be displayed in the Client window. See Figure 3.2.2B.

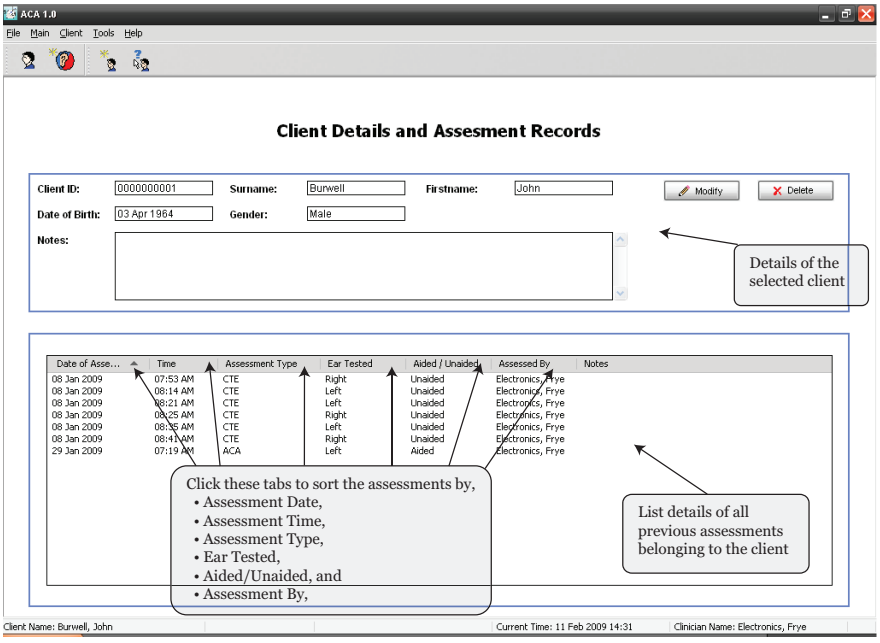
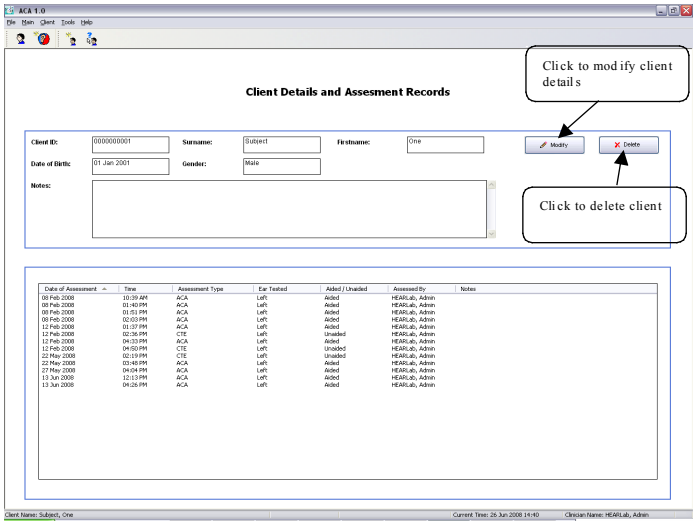

ACA 1.0
File Main Client Tools Help
Client Details and Assesment Records
Client ID: 0000000001
Surname: Burwell
Firstname: John
Modify
Delete
Date of Birth: 03 Apr 1964
Gender: Male
Notes:
Details of the selected client
Date of Asse...
Time
Assessment Type
Ear Tested
Aided / Unaided
Assessed By
Notes
08 Jan 2009 07:53 AM CTE Right Unaided Electronics, Frye
08 Jan 2009 08:14 AM CTE Left Unaided Electronics, Frye
08 Jan 2009 08:21 AM CTE Left Unaided Electronics, Frye
08 Jan 2009 08:25 AM CTE Right Unaided Electronics, Frye
08 Jan 2009 08:35 AM CTE Left Unaided Electronics, Frye
08 Jan 2009 08:41 AM CTE Right Unaided Electronics, Frye
29 Jan 2009 07:19 AM ACA Left Aided Electronics, Frye
Click these tabs to sort the assessments by,
• Assessment Date,
• Assessment Time,
• Assessment Type,
• Ear Tested,
• Aided/Unaided, and
• Assessment By,
List details of all previous assessments belonging to the client
Client Name: Burwell, John
Current Time: 11 Feb 2009 14:31
Clinician Name: Electronics, Frye

Figure 3.2.2B: Client window with assessment records

3.2.3 Modifying details or deleting an existing client



Modifying details of an existing client

1. Follow the steps listed in the previous section to select a client.
2. Click **Modify** in the Client window. The Modify Client Details window will appear. (Figure 3.2.3)

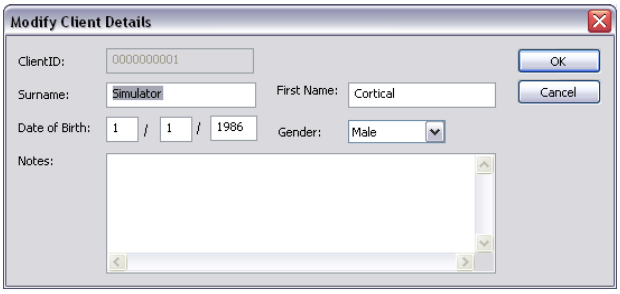
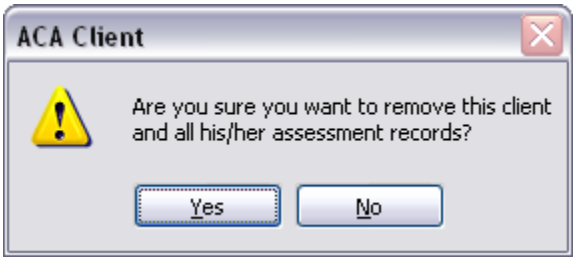


Figure 3.2.3: The Modify Client Details Dialog box

3. Make any desired modifications. (You cannot modify the ClientID.)
4. Click **OK** to save the modifications or **Cancel** to discard them.

Deleting a client

1. Follow the steps listed in the previous section to select a client.
2. Click **Delete** in the Client window. This will open a confirmation window.



3. Click **Yes** to delete the client or **No** to cancel the deletion. **All assessment records belonging to the selected client will also be deleted.**

3.3 Performing an Assessment

An assessment is defined as a series of contiguous tests (referred to as "runs") of different stimuli and presentation levels performed aided/unaided on the same ear, using the same test protocol and presentation method. Each run is defined by the presentation level and the test stimuli. An assessment can have an unlimited number of runs. (It is not possible to repeat the same stimulus at the same level within the same assessment.)

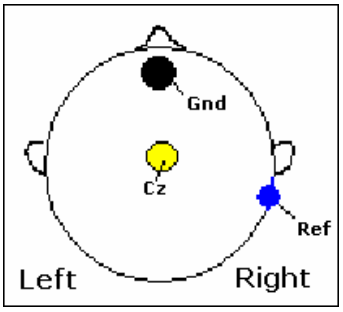
Performing an assessment generally involves the following:

1. Preparing the client for testing.
2. Specifying assessment settings
3. Specifying presentation stimuli and level for each run
4. Checking electrode impedance before testing begins
5. Acquiring evoked cortical responses to presented stimuli

Note: **It must be ensured that calibration of the transducers and free field environment are correct and up-to-date before performing an assessment.** If no calibration has been performed, all testing will be disallowed and you will be advised by an on-screen warning.

3.3.1 Preparing a client for testing

Seat the client comfortably at the test position. Prepare the client's scalp, then place the electrodes on the client's head as per the diagram below:

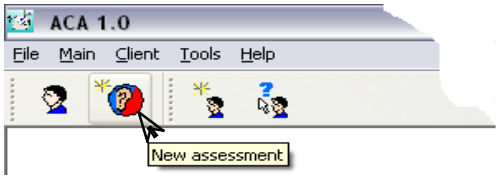


- The **Gnd** (ground) electrode is to be attached on the fore-head
- The **Ref** (reference) electrode is to be attached to the left or right mastoid
- The **Cz** (active) electrode is to be attached to the vertex position

For details on how to prepare a pediatric client for testing, please refer to Appendix A.

3.3.2 Specifying assessment settings

1. Open the New Assessment window. See Figure 3.3.2.
   - Click the **New Assessment** button on the toolbar, or



   - Open the **Main** menu and select **New Assessment.**

Note: If no calibration has yet been performed for free field environment or for other output transducers, a warning message will be displayed on the screen to indicate testing is disallowed for either ACA or CTE, or both.

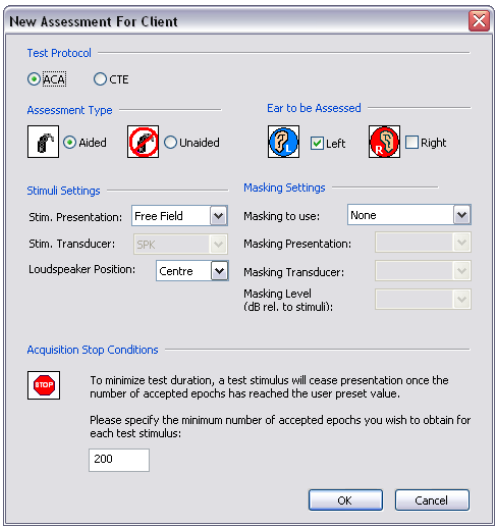
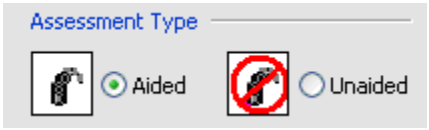


Figure 3.3.2: The New Assessment window

2. Specify the test type:
   - Click the **ACA** for an ACA assessment, OR
   - Click the **CTE** for a CTE assessment

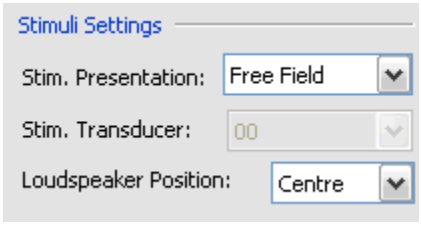
3. Specify whether the test will be Aided or Unaided.



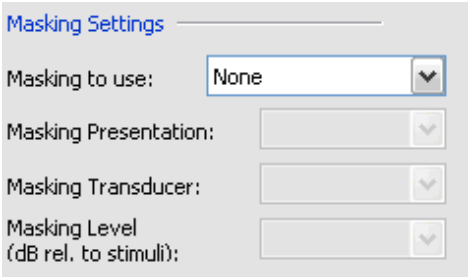
4. Select the ear to be tested. To test binaurally, select both ears.

5. Select the stimuli presentation from the **Stim. Presentation** list:
   - **Free Field** (only available for ACA)
   - **Insert Earphone** (only available for CTE)
   - **Bone Conductor** (only available for CTE)

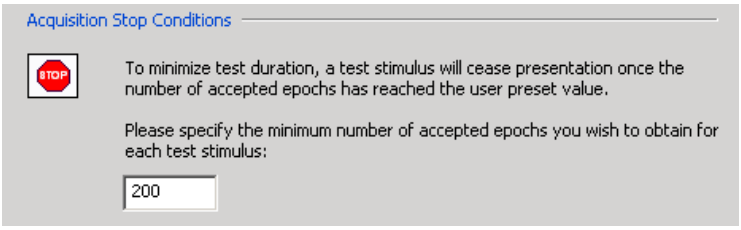
6. For CTE assessments, you must also specify the stimulus transducer used to present the stimuli. Do this by selecting the transducer from the **Stim. Transducer** list (all the calibrated transducers of the transducer type selected from Stim. Presentation will be shown)
7. For ACA assessments, you may need to specify the loudspeaker position (if there is more than one loudspeaker set up). Do this by selecting the position from the **Loudspeaker Position** list.



8. Select the masking type from the **Masking to use** list:
   - **None**
   - **Narrow Band Noise** (only available for CTE)
9. Where applicable, specify the masking presentation from the **Masking Presentation** list:
   - **Insert Earphone**
   - **Bone Conductor**
10. Where applicable, specify the calibrated masking transducer that is to be used to present the masking from the **Masking Transducer** list.
11. Where applicable, select the masking presentation level relative to the stimulus level from the **Masking Level** list: -40 dB, -30 dB, -20 dB, -10 dB, 0 dB, +10 dB.



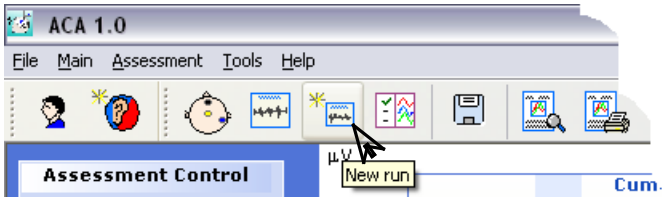
12. Acquisition of cortical responses will stop automatically when the stop criterion is reached. This stop criterion is based on the **minimum number of accepted epochs** for responses to each stimulus. Specify this number as shown below:


Acquisition Stop Conditions
STOP
To minimize test duration, a test stimulus will cease presentation once the number of accepted epochs has reached the user preset value.
Please specify the minimum number of accepted epochs you wish to obtain for each test stimulus:
200

13. Click **OK** to proceed with assessment or **Cancel** if you do not wish to proceed. The New Run window (Figure) will be displayed after **OK** is clicked.

3.3.3 Specifying run settings

1. To open the New Run window (Figure 3.3.3):
   - Click the **New Run** button on the Assessment toolbar, or



   - Open the **Assessment** menu and select **New Run…**

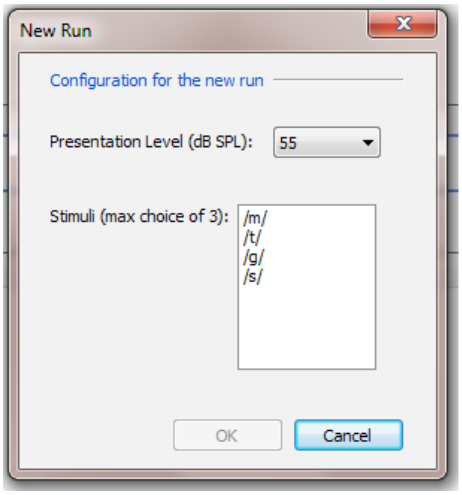
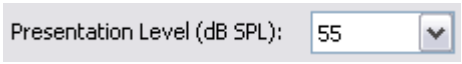


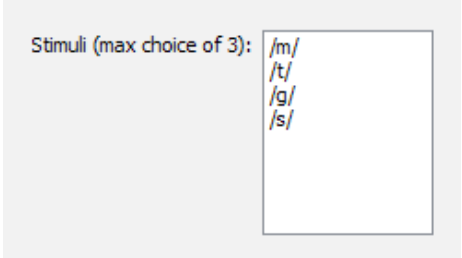
Figure 3.3.3: The New Run window

Note: The New Run window is automatically displayed after a new assessment has been specified.

2. Select the presentation level first using the **Presentation Level** list:
   - **55, 65**, or **75 dB SPL** (for ACA only)
   - **-10 dB HL — 110 dB HL** in 5 dB steps (for CTE only, for **insert earphones**)
   - **-10 dB HL — 70 dB HL** in 5 dB steps (for CTE only, for **bone conductors**)

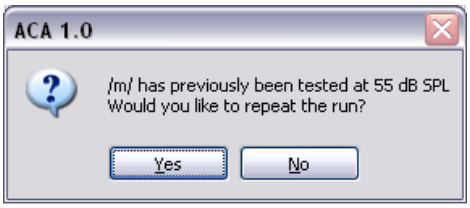


3. Select the stimuli to be presented from the **Stimuli** list:
   - /**m**/, /**t**/, /**g**/, /**s**/ (for ACA only)
   - **500 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz** (for CTE only)



Note: For ACA assessments, up to 3 stimuli can be selected for a single run. For CTE assessments, only one stimulus can be selected at a time.

4. If the selected stimulus has been tested at the selected level, a message will be displayed:

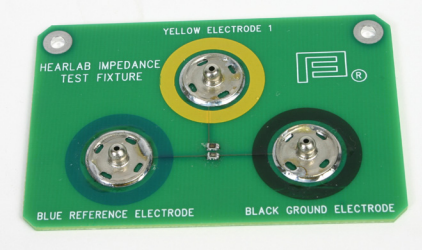


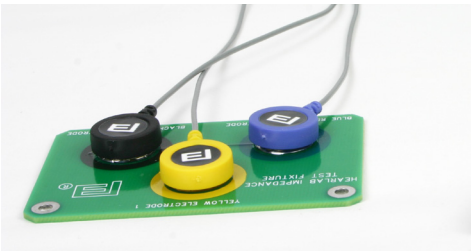
If you would like to repeat the stimulus at the selected level, click **Yes**.

- All other stimuli presented together with the stimulus previously tested will be repeated too, and will be automatically selected.
- Repeated runs cannot be displayed simultaneously. You may select the specific run result to view from the Results Screen (Section).

5. Click **OK** to proceed with the assessment.

3.3.4 Impedance check





A suggestion is made here to periodically check the HEARLab impedance measurement function by use of the HEARLab impedance test fixture shown in the figures above. Matching color codes, snap the individual electrodes to the circuit board and run an impedance check. This may be done before a patient test is initiated by using the tools bar, selecting utilities and then impedance check. Resistors are built into the board that should give indications of slightly over 2000 ohms for both the Cz and Ref electrodes. Each of the impedances are measured against the ground electrode with a small alternating current signal that is applied to the electrodes.

Running this utility is a good check to make sure that the active circuits in the electrodes are functioning correctly.

Note: Do not emerge the electrodes in an impedance test solution, such as salt water, as damage to the active electrodes may result.

After connection of the electrodes to the patient, the HEARLab is set up to automatically go to and perform an impedance check procedure to insure that a good connection is established between the system and the patient. The procedure measures and displays the impedances between the patient and the Cz and Ref electrodes. For reliable potential readings, an impedance of less than 5000 ohms in each electrode connection is recommended.

The colors shown on each of the bar for each electrode represents how good the electrode connection is:

- **Green**: [0 - 5 kΩ], good impedance
- **Yellow**: [5 – 10 kΩ], satisfactory impedance
- **Marginal**: [10 – 15 kΩ], marginal impedance
- **Red**: > 20 kΩ, poor impedance

Monitor the Reference and Cz electrode impedances, and perform any necessary adjustments until both readings give a **Good** impedance status. While the Impedance window is open, impedance measurements will be performed continuously at 1 second intervals.

The disposable electrode sensors have a limited shelf life and become less effective after the packaging has been opened, leading to bad impedance readings. It is recommended to note the date a package of electrode sensors was opened and to dispose of any left over sensors a month after this date.

It may be possible to prolong electrode pad life by storing unused pads in a plastic pouch from which the air has been pressed out before sealing.

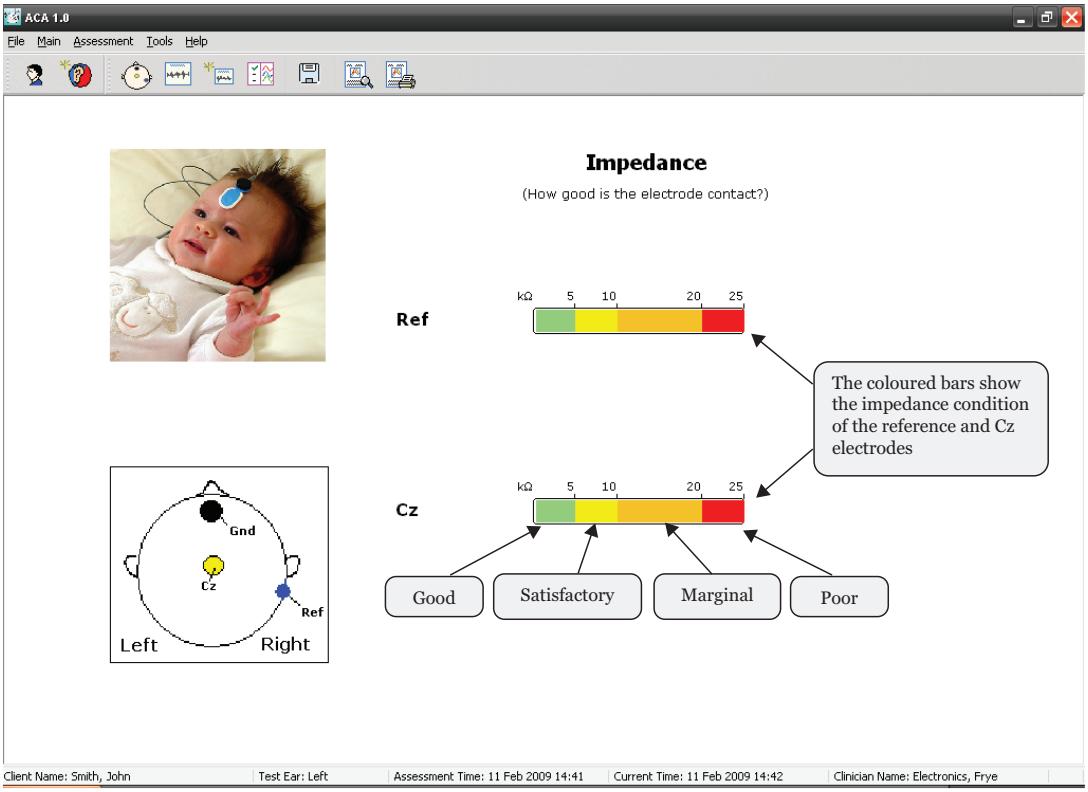
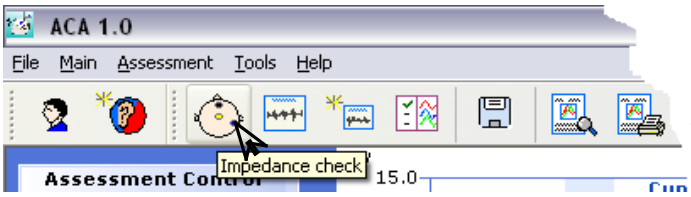


Figure 3.3.4: The Impedance window

To access the Impedance window:

- Click the **Impedance Check** button on the Assessment toolbar, or



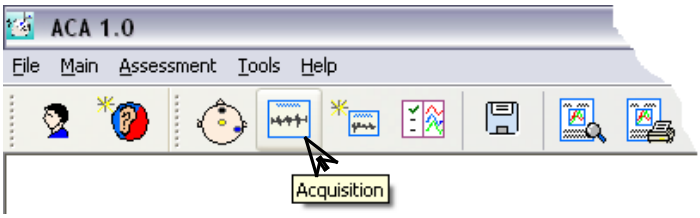
- Open the **Assessment** menu and select **Impedance Check.**

3.3.5 Performing a test

Acquisition for a run can be performed by accessing the Acquisition window.

To access the Acquisition window (Figure 3.3.5):

- Click the **Acquisition** button on the Assessment toolbar, or



- Open the **Assessment menu** and select **Acquisition.**

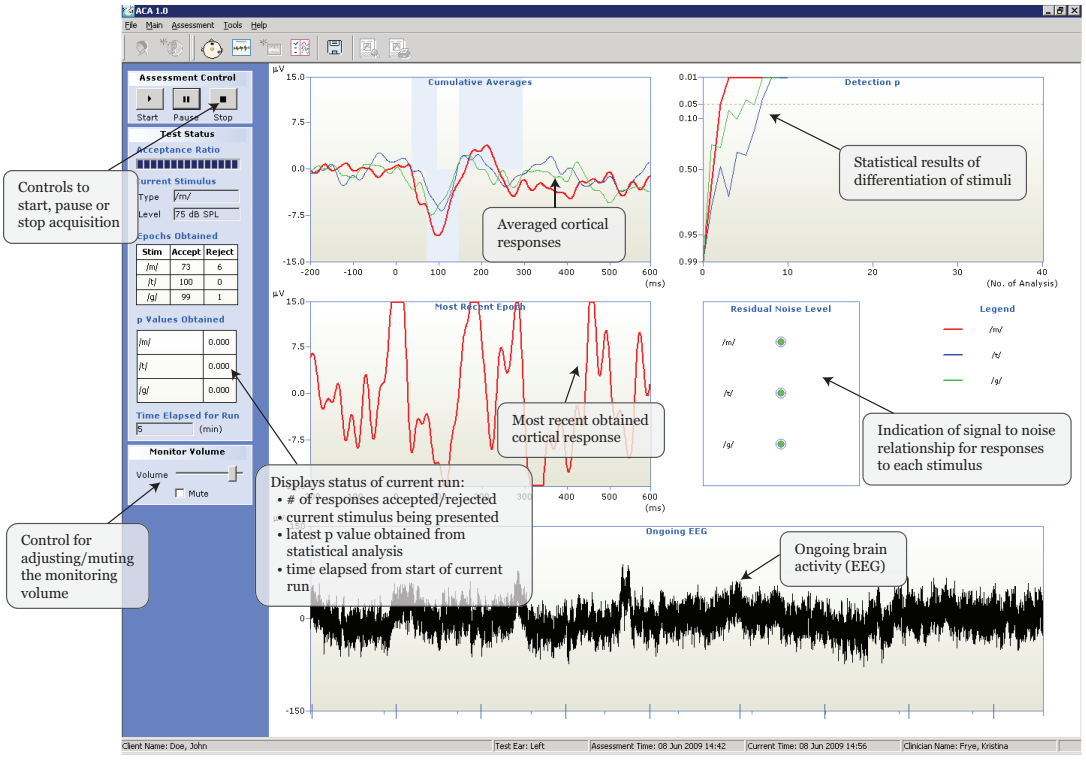

Controls to start, pause or stop acquisition
Averaged cortical responses
Statistical results of differentiation of stimuli
Most recent obtained cortical response
Indication of signal to noise relationship for responses to each stimulus
Displays status of current run:
• # of responses accepted/rejected
• current stimulus being presented
• latest p value obtained from statistical analysis
• time elapsed from start of current run
Control for adjusting/muting the monitoring volume
Ongoing brain activity (EEG)
Cumulative Averages
Detection p
Most Recent Epoch
Residual Noise Level
Legend
Ongoing EEG

Figure 3.3.5: The Acquisition window

Once in the Acquisition screen, acquisition of cortical responses can be started, paused, resumed, or terminated at any time during a run.

Starting the Acquisition

Click the **Start** button to start / resume acquisition or click the **Pause** button to resume acquisition after pausing the current run. During acquisition, statistical analysis for determining the detection of the responses will be performed online.

- While acquisition is progressing, both the menu and toolbars will be disabled.
- Monitor the EEG and the incoming responses. If the EEG is very noisy and many epochs are not being accepted, or if there is no signal, terminate the acquisition immediately and double check all the connections. In the latter case, you may need to restart the both hardware and the application.

Pausing the Acquisition

Click the **Pause** button to pause acquisition for the current run.

Once acquisition has been paused, you may access the Impedance window and the Results window. You may also choose to save the test.

Completing the Acquisition

Click the **Stop** button to stop the test and finish the acquisition for the current run.

Once acquisition has been completed, all toolbar and menu items will be enabled. You may then wish to view results, save results, specify a new run or assessment, or return to the Client winow.

- Acquisition is automatically completed when the specified stop criterion has been met.
- When the Client window is closed, the current assessment is considered complete, and it is not possible to specify a new run for that assessment.

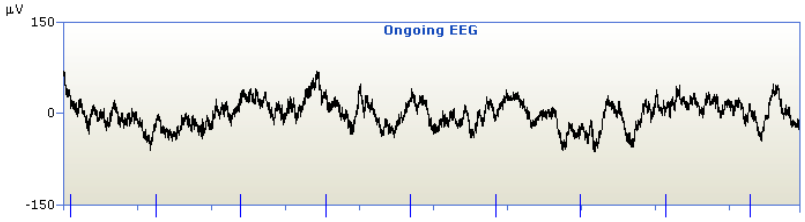
Test Results in the Acquisition window

During the acquisition, the test window will be updated with the acquired data and other results, which include:

- ongoing brain activity
- the most recent response to the presented stimulus
- the averaged responses to the presented stimuli
- statistical analysis results for response detection
- the number of responses accepted and rejected for each stimulus
- the time elapsed for the current run
- the Q factor (a signal to noise indicator) for each stimulus

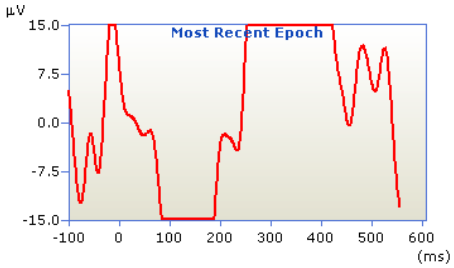
Ongoing brain activity

The ongoing gross brain activity is displayed on the Ongoing EEG plot:



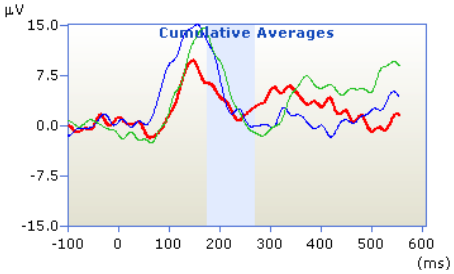
Most recent response

The most recent response to the presented stimulus is displayed in the Most Recent Epoch plot:



Averaged responses

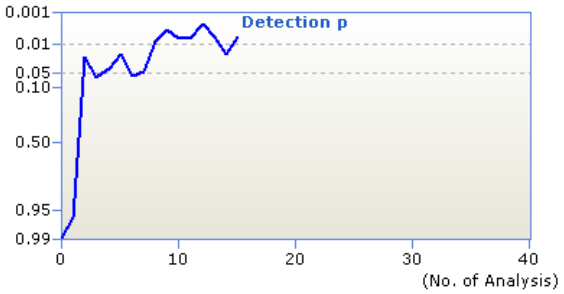
The averaged responses to all the presented stimuli are displayed in the Cumulative Averages plot. This data is displayed for informational purposes only. You should normally use the statistical analysis results to determine CAEP presence.



The shaded region shown in the averaged response graph indicates the typical latency range for the patient's age. This is for informational purposes only. See Section 7.3.5 for more information.

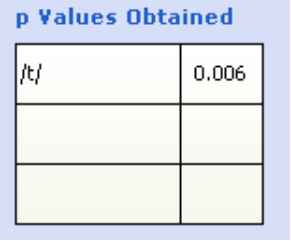
Statistical analysis results

The ongoing statistical analysis results are displayed in the 'Detection p' plots. The detection p-value is the probability of obtaining data as or more extreme than what was observed, under the assumption that there was no cortical response. A low p-value indicates that the observed recording would have been unlikely to occur had there been no cortical response, and therefore provides evidence that a cortical response was very likely present.



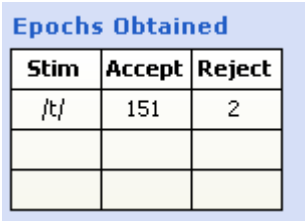
A specificity of 95% (false detection rate of 5%) will be achieved if a cortical response is taken to be present whenever $p < 0.05$ after the pre-defined number of epochs has been collected. To reduce testing time without excessively increasing the false detection rate above 5%, we recommend that a cortical response is taken to be present if $p < 0.001$ at any time during the run (indicated in HEARLab by p=0.000), at which point the run can be stopped, or if $p < 0.05$ after the pre-defined number of epochs has been collected.

The numerical p-value of the latest statistical analysis can be viewed on the left hand panel of the screen:



In some cases the statistical analysis will suggest the presence of a CAEP response even when the presence of a CAEP waveform is not immediately apparent to the clinician. Conversely, an absence of a CAEP could be caused by too much residual noise causing visually prominent peaks to not be reliable indicators of an actual CAEP. See the section on residual noise below for information on interpreting the statistical analysis of the signal.

Number of accepted / rejected responses



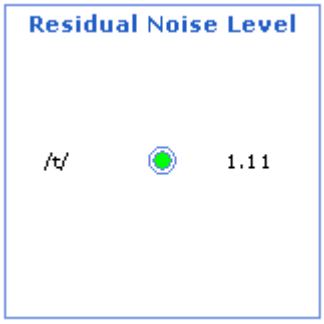
HEARLab rejects any epoch which contains a sample value either equal or greater than +150 μV or equal or less than -150 μV. The number of accepted and rejected responses for each presented stimulus can be viewed on the left hand panel of the screen:

It is recommended to not let the acceptance ratio (the number of accepted epochs divided by the number of rejected epochs) become smaller than 1/2. If this is the case, it might be better to reposition or calm down the subject, and start recording a retest.

Residual Noise

The 'Residual Noise Level' indicator shows how noisy the recording has been. The indicator estimates the noise amplitude that is left in the averaged epoch. The residual noise usually decreases in value as the number of epochs increase. This is similar to the decreasing noise visible in the visual representation of the grand average waveform as more epochs are averaged during a recording.

The indicator is expected to be red at the start of an acquisition run. With good electrode contacts and favorable subject test conditions, the indicator is likely to change from red to yellow/orange and then green. Additional to its use to monitor the status of the recording, it provides guidance on interpreting the result of the statistical analysis. At the end of any preset number of epochs for the recording run, interpret the indicator as follows:



A red colour indicates a high level of noise in the recording.

The hearing threshold corrections for adults and detection sensitivities for infants, as described in Sections 8.4.2 and 8.4.3 respectively, would then not be expected. These studies have been based on residual noise levels that returned a green traffic light at the end of the recording. Practically, when HEARLab indicates a response is present (by showing a p-value smaller than 0.05), the answer can be readily accepted. However, when HEARLab indicates no response is present ($p > 0.05$), it is possible the background noise obscures the CAEP, even when there is an actual CAEP present: the noise is just too large to allow detection of the CAEP. It is recommended to do a retest after the client has been repositioned or settled down. If this is not possible, increase the number of predefined epochs to collect.

A yellow/orange colour indicates a moderate level of noise in the recordings, and indicates the traffic light indicator is likely to turn green when more epochs are collected.

A green colour indicates a low level of noise in the recording. The hearing threshold corrections for adults and detection sensitivities for infants are then expected to be those described in Sections 8.4.2 and 8.4.3 respectively.

Even with artifact rejection, which only removes extreme values in the EEG, a traffic light system is desirable, as the range of possible noise levels originating from subjects is large. For example, it is possible that a subject generates a continuous elevated background noise without extremes when compared to another subject who is much quieter. In both cases the artifact rejection will not filter away these types of noise.

To view the actual value of the residual noise level, move the mouse over the window and hover above a stimulus label, and the value will be displayed next to the indicator light.

If the test changes from a high noise state (as evidenced by the patient's behavior, a large amplitude on the continuous EEG record, and a high residual noise in the traffic light window) to a lower noise state (as evidenced by the patient's behavior and a smaller amplitude on the continuous EEG record) as a test progresses, it is possible that a low residual noise in the averaged response will be obtained more quickly if the test is restarted than if the test is continued.

3.4 CAEP Wave Morphology

CAEP waveforms are highly individual and vary greatly from person to person. This section contain a few examples. Note the typical appearance of a single positive peak in the infant ACA example of figure 3.4B, and the marked negativity followed by a clear positive peak that is typical in adult cases shown in figure 3.4A and 3.4C.

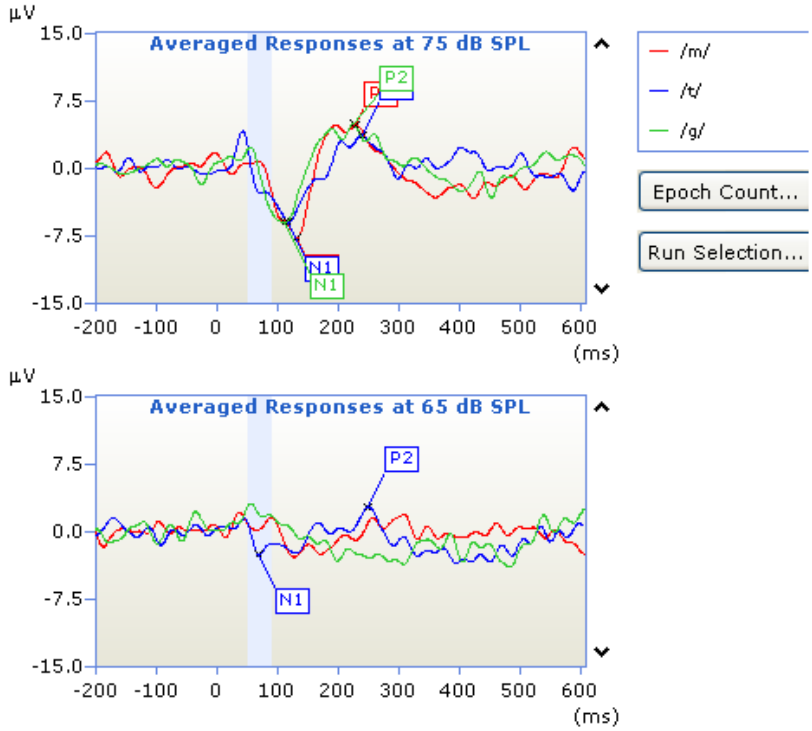


Figure 3.4A: Example of a hearing impaired adult ACA

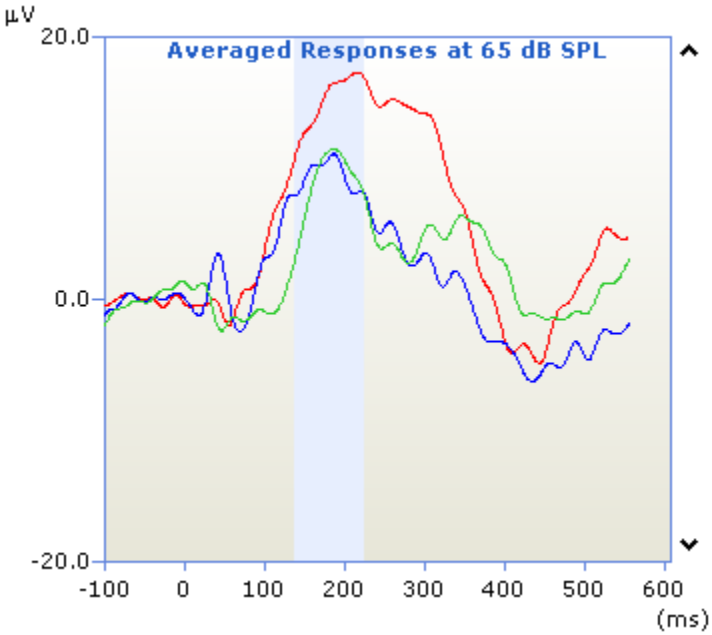


Figure 3.4B: Example of a normal hearing infant ACA

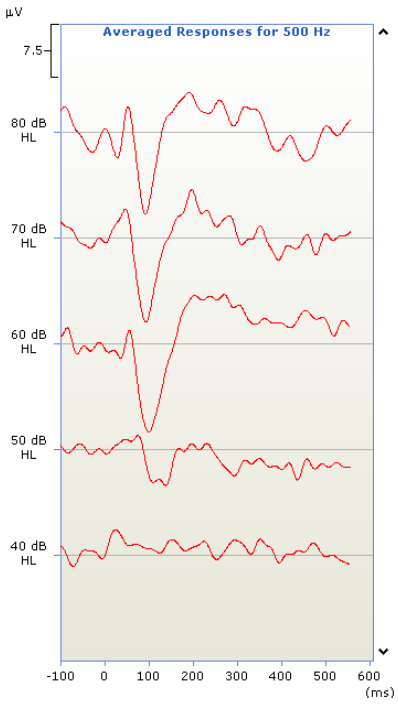


Figure 3.4C: Example of a hearing impaired adult CTE at 500 Hz

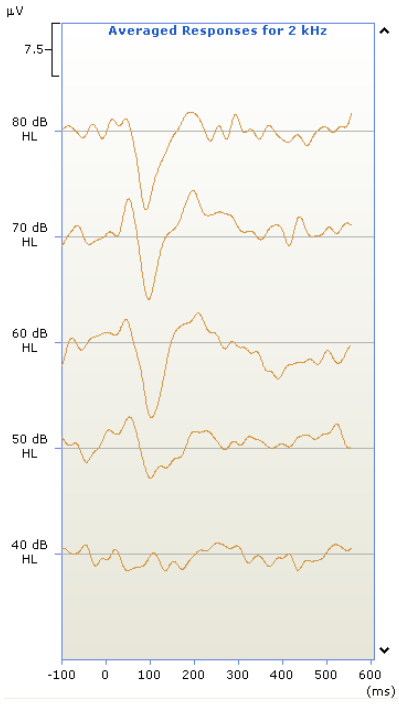


Figure 3.4D: Example of a hearing impaired adult CTE at 2000 Hz

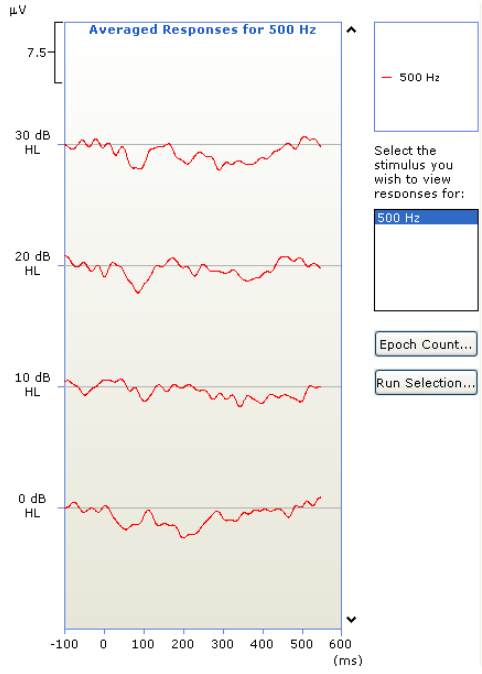


Figure 3.4E: Example of a normal hearing adult CTE at 500 Hz

Figure 3.4F: Example of a normal hearing adult CTE at 2000 Hz

3.5 The Results Window

The Results window can be accessed to view results for the current assessment or for previously saved assessments. See Figure 3.5.

Assessment results consist of:

- a summary of assessment settings (e.g. whether it was aided/unaided, test ear etc)
- the statistical analysis results
- the averaged responses to the presented stimuli at different levels
- any additional comments about the assessment

Assessment and run settings can be viewed at any time during the assessment, including when acquisition is progressing. A summary of the assessment settings is located on the located on the Results window.

- Detailed assessment settings can be viewed by opening the **Assessment** menu, pointing at **View Settings**, and selecting **Assessment.**
- The current run's settings can be viewed by opening the **Assessment** menu, pointing at **View Settings** and selecting **Run.**

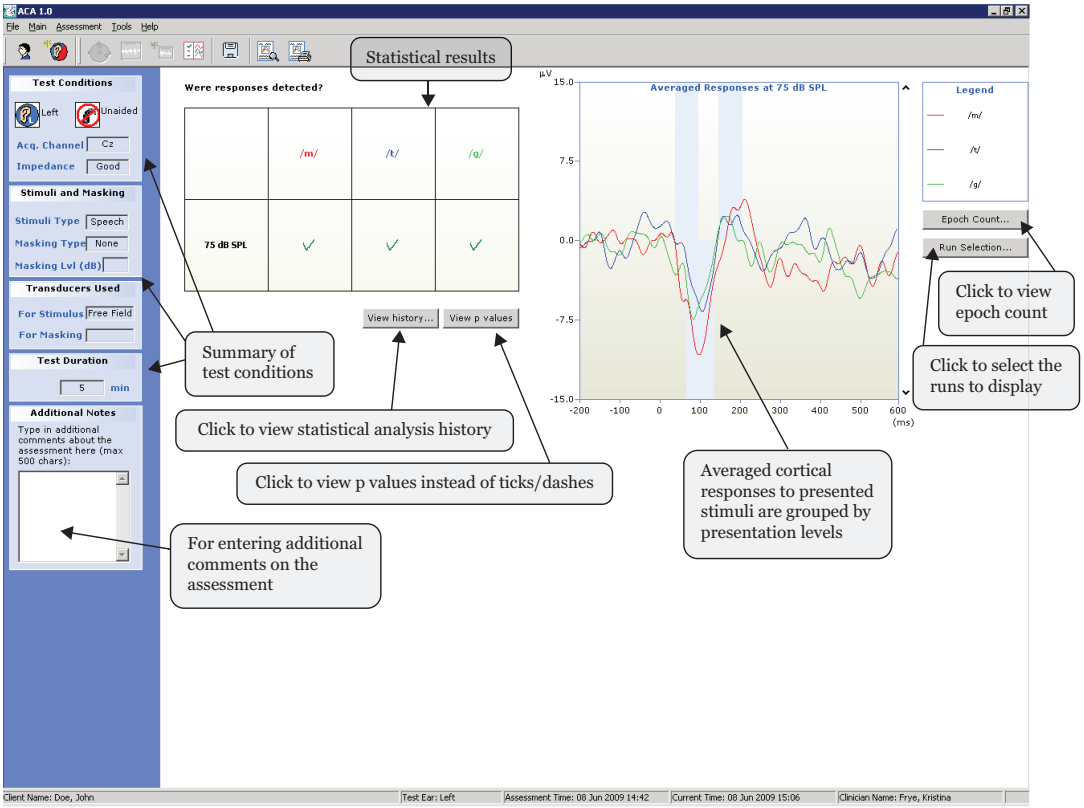
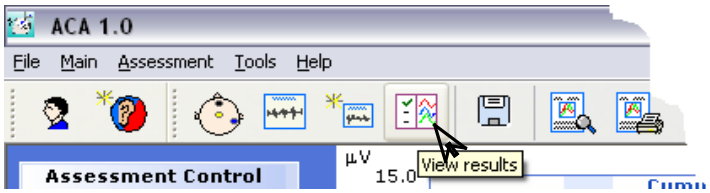

Statistical results
Summary of test conditions
Click to view statistical analysis history
Click to view p values instead of ticks/dashes
For entering additional comments on the assessment
Averaged cortical responses to presented stimuli are grouped by presentation levels
Click to view epoch count
Click to select the runs to display

Figure 3.5: The Results window

3.5.1 Accessing the Results window

To access the Results window during the time of an assessment:

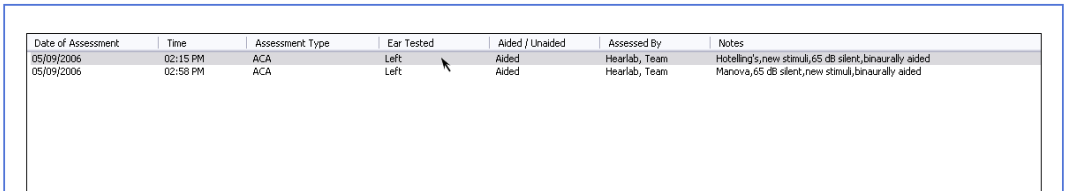
- Click the **Results** button on the Assessment toolbar, or



- Open the **Assessment menu** and select **View Results**

To access a client's previous assessment results:

1. Open the Client window. The selected client's previous assessments are displayed in a list.
2. Double-click on the assessment you wish to view, or right click on it and select **View Assessment**.

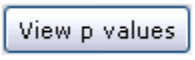


3.5.2 Adding notes

To add notes to the assessment, type them into the **Additional Notes** box. A maximum of 500 characters can be used.

3.5.3 Viewing the Statistical Analysis

Statistical analysis results for detection of responses are displayed in a tabular format for each stimulus at each presentation level (See Figure 3.5.3A). By default, checkmarks and dashes are used to represent a significant or an insignificant result respectively.



Use this button to view the actual p value from the last analysis performed.

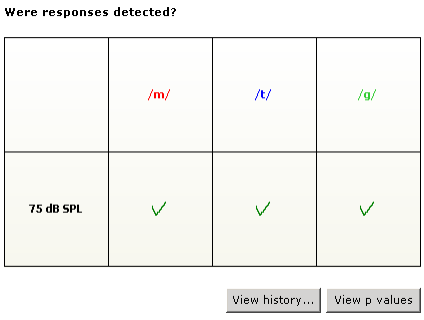
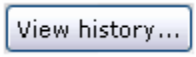


Figure 3.5.3A: Statistical Analysis on the Assessment

Using the Statistical Analysis History Window



Use this button to view the results of the ongoing statistical analysis during the acquisition.

To view the numerical values of a particular curve in the Statistical Analysis History window, click on the curve. The mouse cursor will become a +, the selected trace will be bolded, and a rectangular box will appear next to the cursor with the p value obtained at the nth analysis. See Figure B. Double-click to return to normal mouse operations.

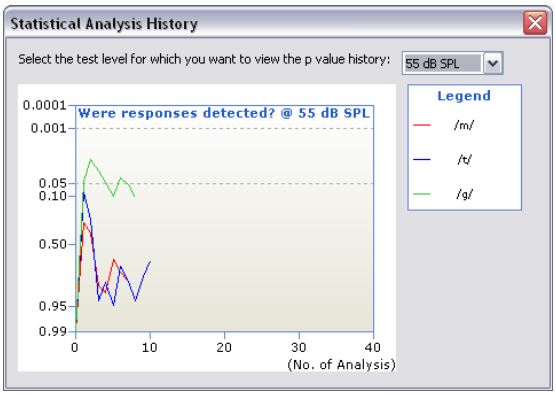
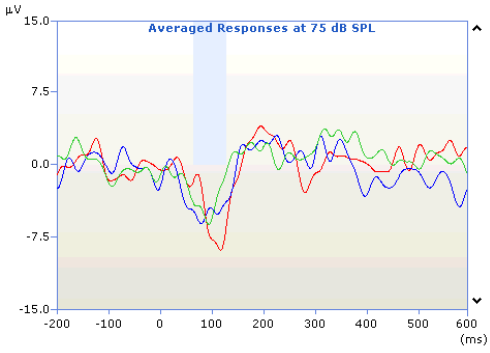


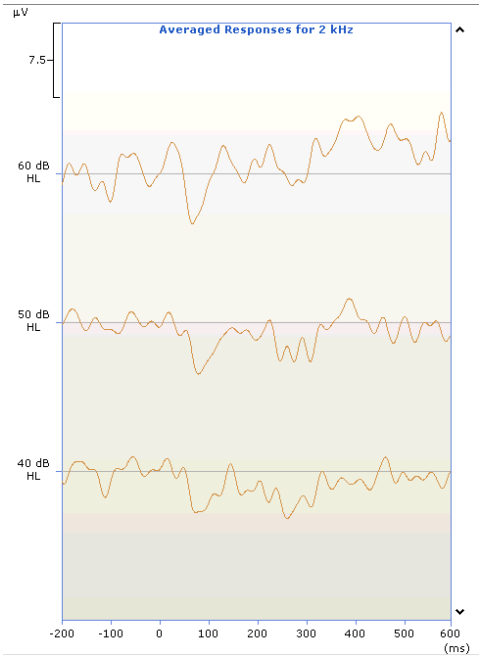
Figure 3.5.3B: The Statistical Analysis History window

3.5.4 Viewing Averaged Responses

For ACA assessments, averaged responses to each stimulus are grouped by stimulus presentation level. Thus, each graph displays the averaged responses to the stimuli that have been presented at the indicated presentation level.



For CTE assessments, averaged responses are grouped by stimuli, Thus, each graph displays the averaged responses to the indicated stimulus at various presentation levels.



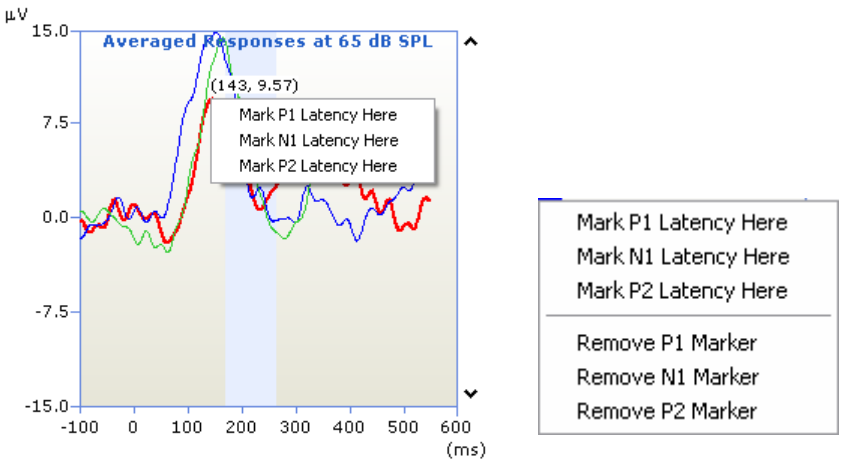
Selecting an Averaged Response

To select an averaged response trace, move the mouse over the trace of the response of interest. Left-click once on the trace to select it. The mouse cursor will become a +, the selected trace will be bolded, and a rectangular box will appear next to the cursor with latency and amplitude information displayed. You can then move the cursor along the trace to view the values for a particular point on the trace. Double-click to return to normal mouse operation.

Marking Latencies on an Averaged Response

To mark latencies on an averaged response:

1. Select the trace.
2. Move the cursor to the appropriate peak or trough and right-click on it. A menu will appear.
3. Select the appropriate marker **(P1, N1** or **P2)**. It will appear on the graph where you clicked on the graph.



To remove a latency marker, right-click on the trace and select the marker to remove.

Note: The latency markers will be displayed with latency and amplitude values only when the trace is selected.

3.5.5 Viewing the Epoch Count

Use this button to access information about the number of accepted/rejected responses for each stimulus at the levels it was presented, This will open the Epoch Count window. See Figure 3.5.5.

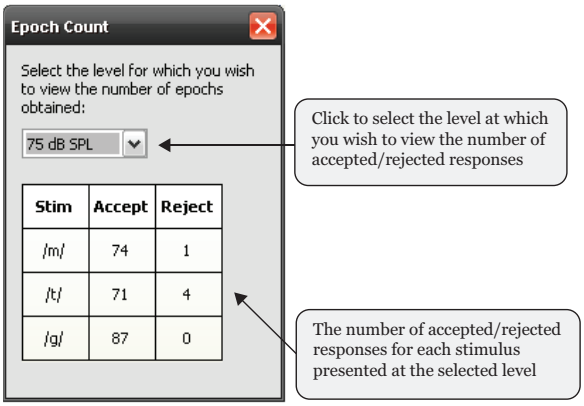


Figure 3.5.5: Epoch Count window

Use the list to select the presentation level at which you wish to view the epoch counts.

3.5.6 Changing the Run Selection

Even if multiple runs have been performed with a particular stimulus and ampitude, only one can be displayed at a time. To select which run is displayed, use the **Run Selection** button. See Figure 3.5.6.

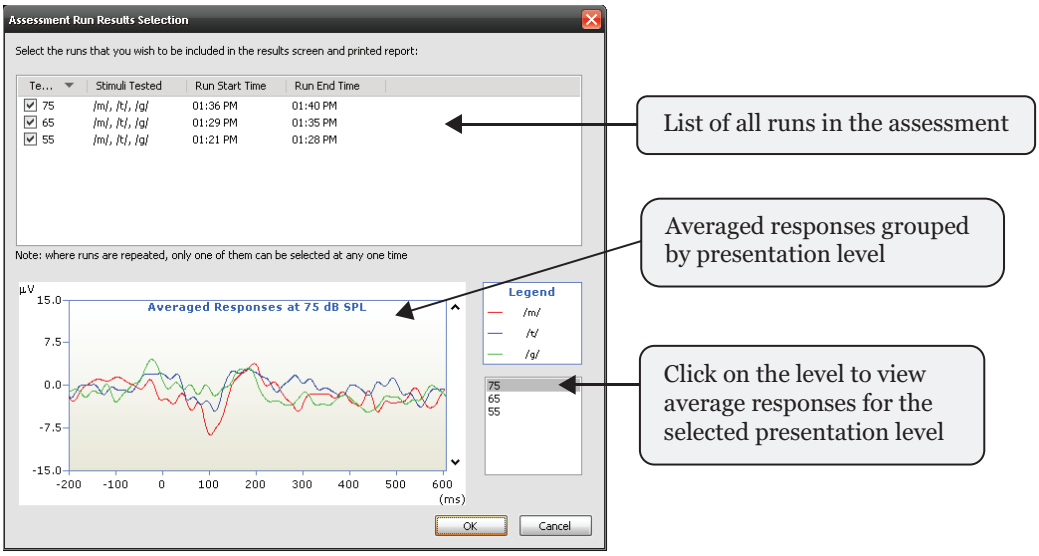

Assessment Run Results Selection
Select the runs that you wish to be included in the results screen and printed report:
Te...
Stimuli Tested
Run Start Time
Run End Time
75 /m/, /t/, /g/ 01:36 PM 01:40 PM
65 /m/, /t/, /g/ 01:29 PM 01:35 PM
55 /m/, /t/, /g/ 01:21 PM 01:28 PM
Note: where runs are repeated, only one of them can be selected at any one time
µV
15.0
7.5
0.0
-7.5
-15.0
Averaged Responses at 75 dB SPL
-200 -100 0 100 200 300 400 500 600
(ms)
Legend
/m/
/t/
/g/
75
65
55
OK
Cancel
List of all runs in the assessment
Averaged responses grouped by presentation level
Click on the level to view average responses for the selected presentation level

Figure 3.5.6: Run Selection window

Select the runs you wish you use. The plot window will be updated accordingly as you make your selections. Click **OK** when you have finished your selections.

3.5.7 Viewing Residual Noise

To view the residual noise level values for the run:

1. Open the Run Selection window.
2. Right-click on the run in the run list and select **View Residual Noise Values...** The Residual Noise for Run window will be displayed. See Figure 3.5.7. The displayed value shows how noisy the recording has been. The indicator estimates the noise amplitude that is left in the averaged epoch.

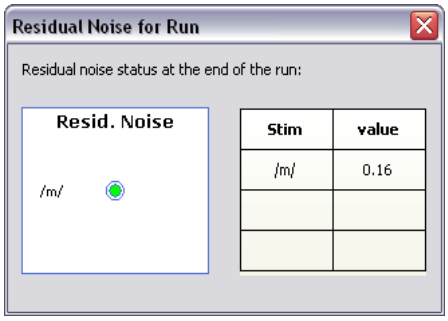


Figure 3.5.7: Residual Noise for Run window

3.5.8 Exporting Run Results

To export run results:

1. Open the Run Selection window.
2. Right-click on the run in the run list and select **Export Run Data…** A Save As window will appear.
3. Specify the location and name of the file to export the results.
4. Click **Save** to save exported run data. The data will be saved as a text file.

The exported file will be in the following format:

[Client]
ClientID={value}
Client Name= {value}

[Run Settings]
Level Tested={value}
Level Unit={dB SPL / dB HL}
Test date={dd mmm yyyy}
Test time={value}

[Averaged Responses Data]
Stimulus={value}
# of samples={value}
# of accepted ={value}
Data={values}

[Statistical Analysis History for Detection p]
Stimulus={value}
p values={values}

[Residual Noise History]
Stimulus={value}
Residual noise values={values}

3.5.9 Deleting a Run

To remove a run from an assessment:

1. Open the Run Selection window.
2. Right-click on the run in the run list and select **Delete Run…**
3. Confirm that you want to delete the run.

3.6 Printing Assessment Reports

The assessment reports for ACA and CTE assessments are slightly different from each other in terms of layout, but they both present the same information. You may choose to look at the print preview of the assessment report before printing it out, or you may print it directly without a preview.

3.6.1 Previewing the Print Report

To access print preview before printing, you can either click the **Print Preview** button on the Assessment toolbar or open the **Assessment** menu, point at **Report**, and select **Print Preview.** See Figure 3.6.1.

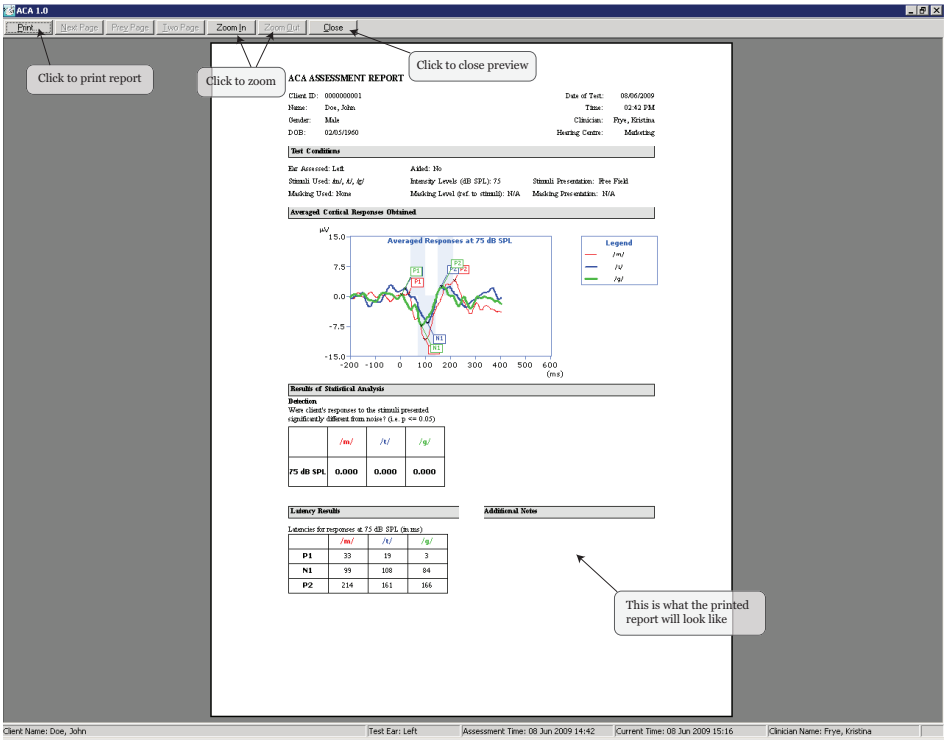


Figure 3.6.1: Print Preview

To print results, click **Print** on the top of the Print Preview window. This will close the Print Preview window, display the Results window, and open a Print window. Choose the desired printer and click **OK** to print.

3.6.2 Printing the Report without Preview

To print the test report without previewing, click the **Print Report** button on the Assessment toolbar, or open the **Assessment** menu, point at **Report**, and select **Print**. This will open a Print window. Choose the printer you want to use and click **OK**.

3.6.3 The ACA Assessment Report

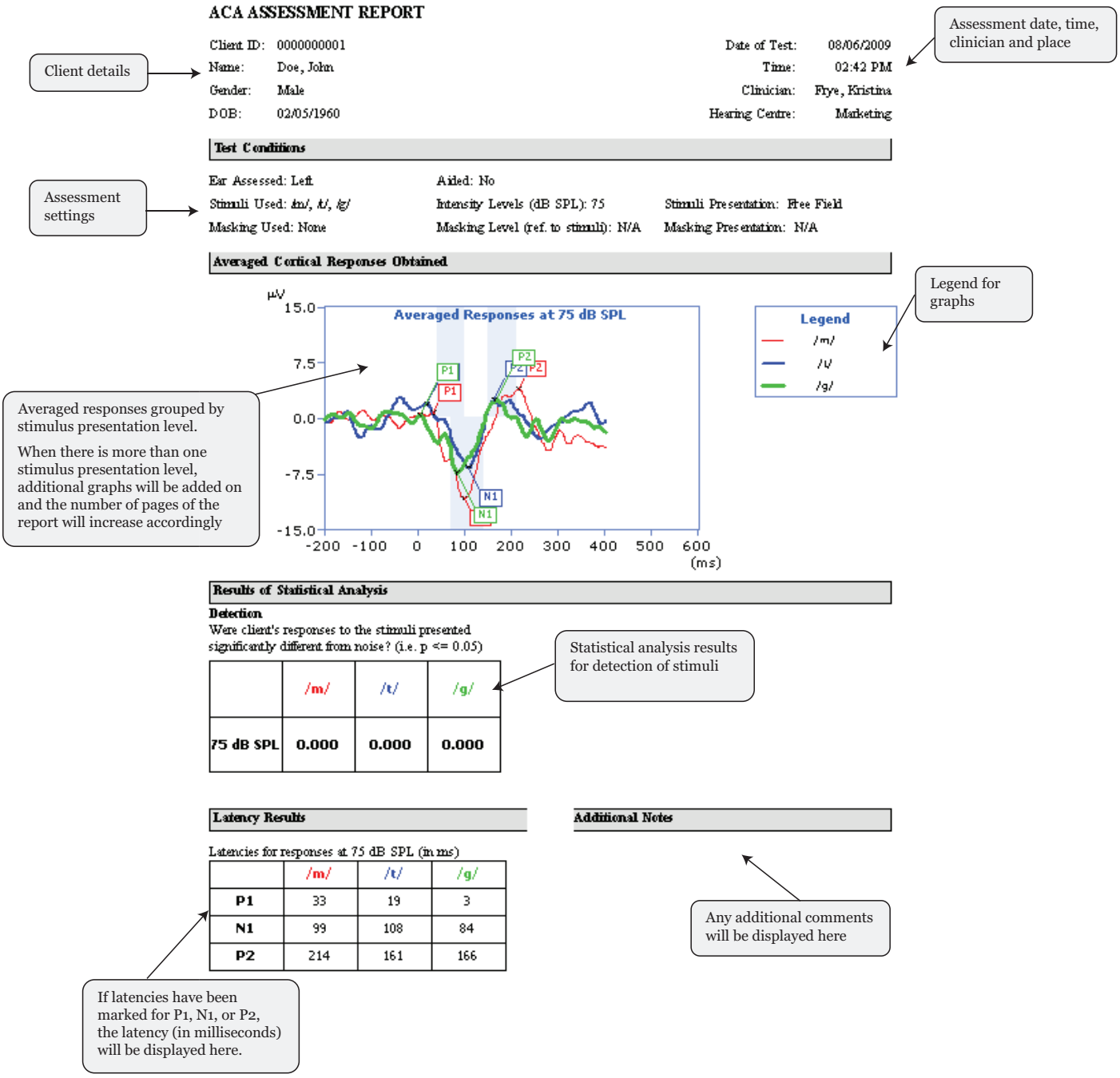
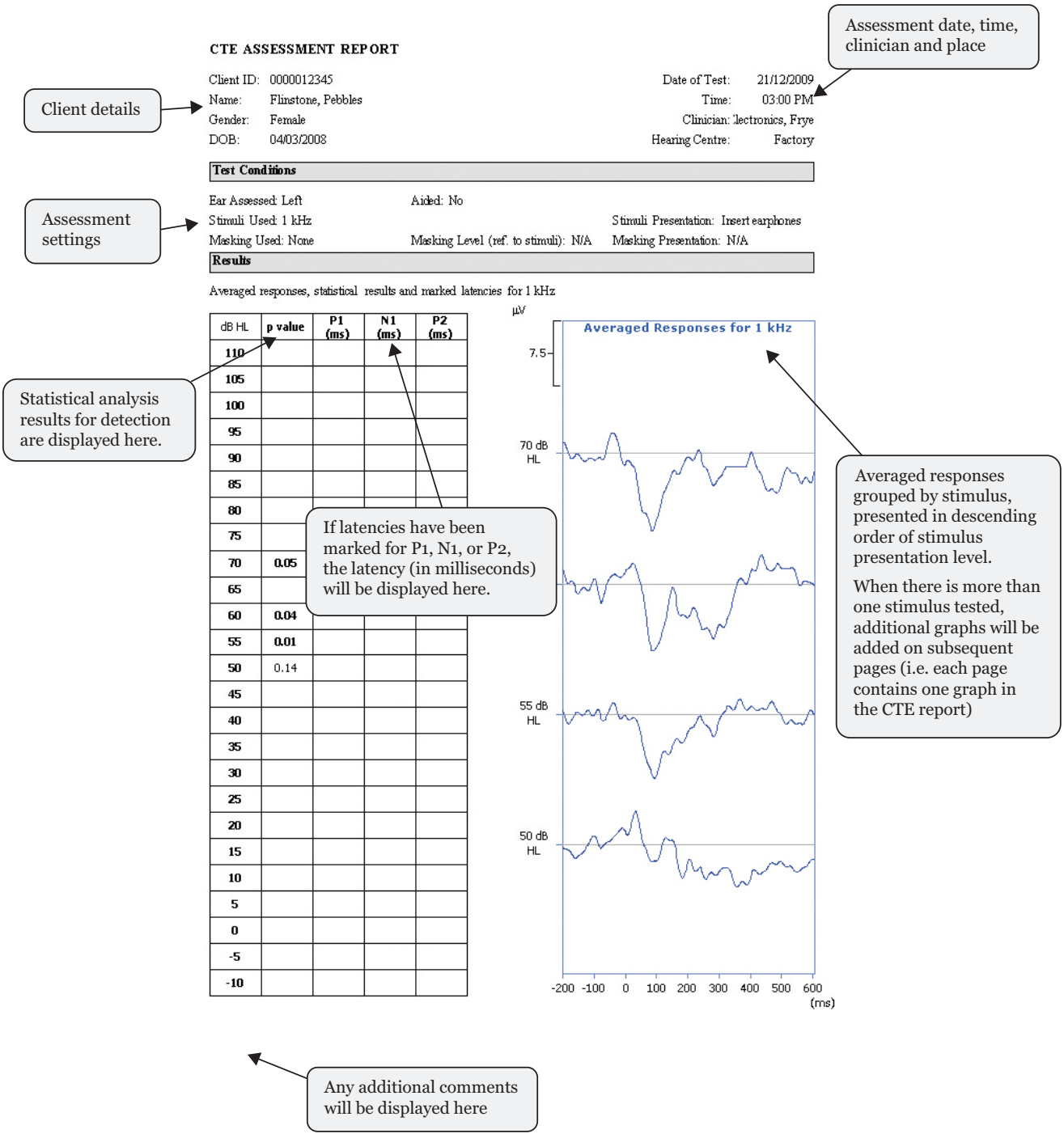

ACA ASSESSMENT REPORT
Client ID: 0000000001
Name: Doe, John
Gender: Male
DOB: 02/05/1960
Date of Test: 08/06/2009
Time: 02:42 PM
Clinician: Frye, Kristina
Hearing Centre: Marketing
Test Conditions
Ear Assessed: Left
Aided: No
Stimuli Used: /m/, /t/, /g/
Intensity Levels (dB SPL): 75
Stimuli Presentation: Free Field
Masking Used: None
Masking Level (ref. to stimuli): N/A
Masking Presentation: N/A
Averaged Cortical Responses Obtained
Averaged Responses at 75 dB SPL
Legend
/m/
/t/
/g/
Results of Statistical Analysis
Detection
Were client's responses to the stimuli presented significantly different from noise? (i.e. p <= 0.05)
/m/ /t/ /g/
75 dB SPL 0.000 0.000 0.000
Latency Results
Latencies for responses at 75 dB SPL (in ms)
/m/ /t/ /g/
P1 33 19 3
N1 99 108 84
P2 214 161 166
Additional Notes
Client details
Assessment settings
Assessment date, time, clinician and place
Legend for graphs
Averaged responses grouped by stimulus presentation level.
When there is more than one stimulus presentation level, additional graphs will be added on and the number of pages of the report will increase accordingly
Statistical analysis results for detection of stimuli
Any additional comments will be displayed here
If latencies have been marked for P1, N1, or P2, the latency (in milliseconds) will be displayed here.

Figure 3.6.3: The ACA Assessment Report

3.6.4 The CTE Assessment Report


Assessment date, time, clinician and place
CTE ASSESSMENT REPORT
Client details
Client ID: 0000012345
Name: Flinstone, Pebbles
Gender: Female
DOB: 04/03/2008
Date of Test: 21/12/2009
Time: 03:00 PM
Clinician: lectronics, Frye
Hearing Centre: Factory
Test Conditions
Assessment settings
Ear Assessed: Left
Aided: No
Stimuli Used: 1 kHz
Stimuli Presentation: Insert earphones
Masking Used: None
Masking Level (ref. to stimuli): N/A
Masking Presentation: N/A
Results
Averaged responses, statistical results and marked latencies for 1 kHz
Statistical analysis results for detection are displayed here.
If latencies have been marked for P1, N1, or P2, the latency (in milliseconds) will be displayed here.
Averaged Responses for 1 kHz
µV
7.5
70 dB HL
55 dB HL
50 dB HL
-200 -100 0 100 200 300 400 500 600
(ms)
Averaged responses grouped by stimulus, presented in descending order of stimulus presentation level.
When there is more than one stimulus tested, additional graphs will be added on subsequent pages (i.e. each page contains one graph in the CTE report)
Any additional comments will be displayed here

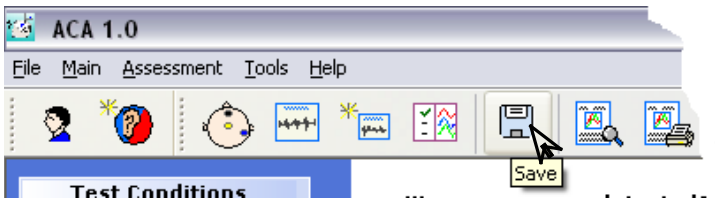
dB HL	p value	P1 (ms)	N1 (ms)	P2 (ms)
110				
105				
100				
95				
90				
85				
80				
75				
70	0.05			
65				
60	0.04			
55	0.01			
50	0.14			
45				
40				
35				
30				
25				
20				
15				
10				
5				
0				
-5				
-10				

Figure : The CTE Assessment Report

3.7 Saving Assessment to Database

To save the assessment runs and modifications (e.g. latencies, comments):

- Click **Save** on the Assessment toolbar, or



- Open the **Assessment** menu and select **Save.**

3.8 Deleting Assessments

To delete a client's previous assessment:

1. Open the Client window.
2. Right-click on the assessment you want to delete.
3. Select **Delete Assessment…**
4. Confirm the deletion.

Sound Field Calibration

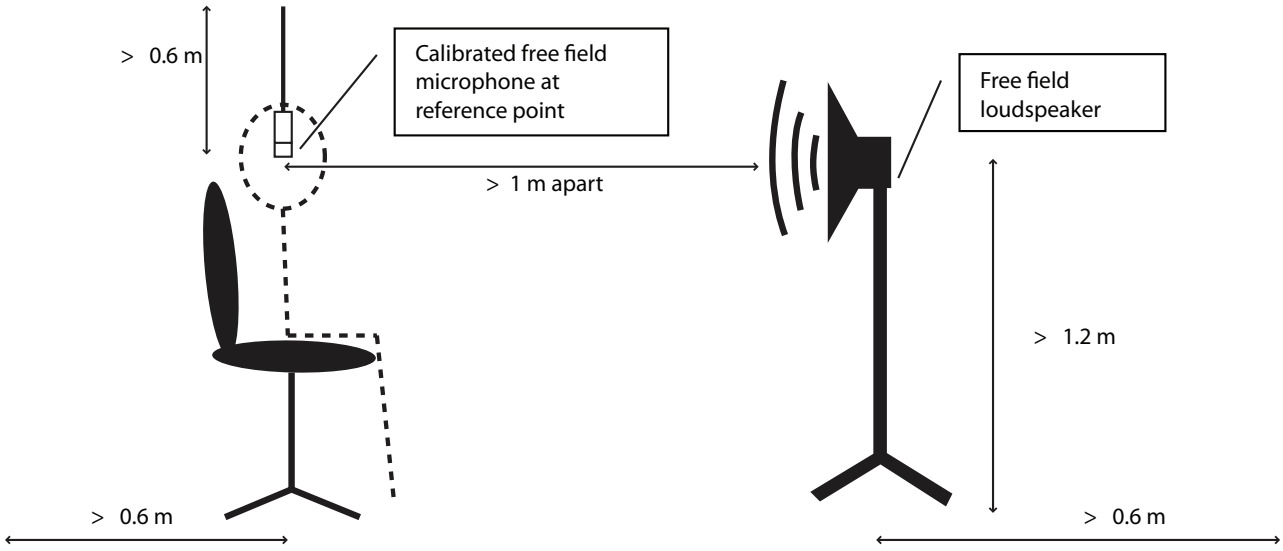
This chapter describes how to calibrate the sound field for ACA measurements. We recommend that this simple procedure be performed on a daily basis for best accuracy of test results.

These instructions assume that control microphone has been calibrated. The control microphone calibration needs to be performed by an experienced technician using proper equipment. See the Hearlab System Maintenance Manual for instructions on performing the control microphone calibration as well as calibration of the insert earphones and bone vibrator for CTE measurements.

The sound field calibration process involves obtaining the frequency response of a free field environment (room acoustics + sound field frequency response) and equalising the complex signals that are to be presented in that environment.

4.1 Calibration Setup

To set up the room for free field calibration, have everything set up as you would for an ACA assessment. Place the control microphone at the approximate location where a client's head is likely to be situated.



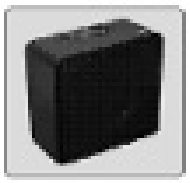
Typical room setup for free field calibration

4.2 Free Field Calibration Wizard

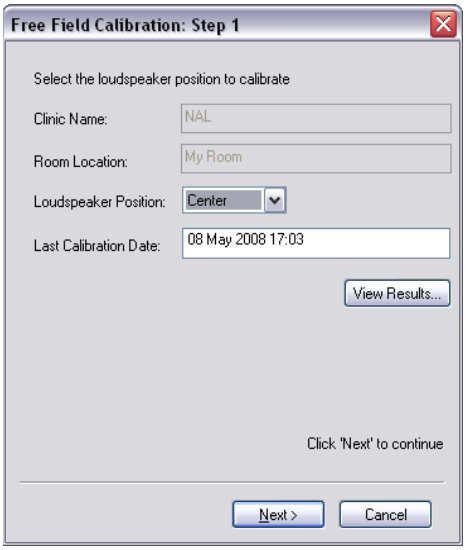
The Free Field Calibration Wizard will guide you step-by-step through the calibration process.

Warning: When the sound field is calibrated, the old calibration results will be replaced with the new results. See Section 4.3 for instructions on how to keep a permanent record of old calibration results.

1. Open the Calibration window by pressing CTRL+SHIFT+ALT+K.
2. Click the **Free Field** button. This will open the Free Field Calibration Wizard.



Free field button



The Free Field Calibration Wizard

Specify the loudspeaker position in the room by using the **Loudspeaker Position** list. The last calibrated position is selected by default.

Loudspeaker position selection box

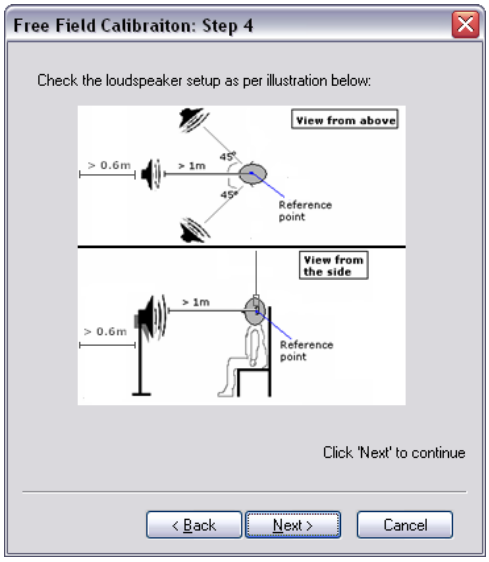
3. Click **Next** to proceed to the next step in the wizard.
4. Specify the loudspeaker to be calibrated by using the **Loudspeaker ID** list. If the loudspeaker you want to calibrate is not listed, see the Maintenance Manual for instructions on adding a new loudspeaker to the list.

Loudspeaker selection box

5. Specify the distance between the loudspeaker and the test position (where the control microphone has been placed).

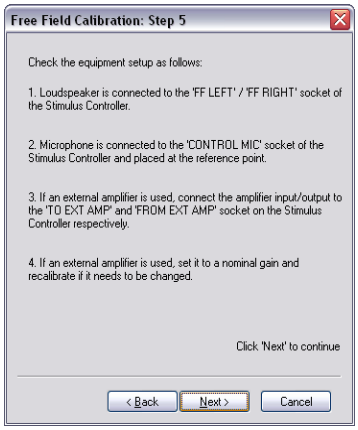
Distance beteween microphone and speaker

6. Click **Next** to proceed to the next step in the calibration wizard.
7. Select **Automatic (using a calibrated microphone).** For instructions on how to calibrate using a sound level meter instead of the control microphone, see the HEARLab System Maintenance manual.
8. Use the list to specify the microphone that is to be used in the calibration process. This field will normally not be changed.
9. Click **Next** to proceed to the next step in the calibration wizard. This step contains a diagram on how to set up the equipment for the calibration process.



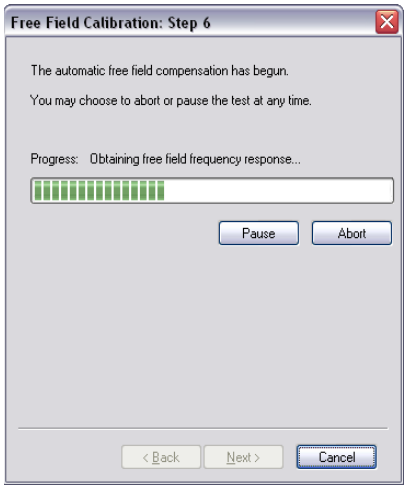
The Free Field Calibration Wizard: Room Setup

10. Click **Next** to procede to the next step in the calibration wizard. This step contains a list of all the connections to check before performing the calibration.
    - Make sure the control microphone (used in the calibration process) is plugged into the **Control Mic** socket of the Stimulus Controller (SC) and properly placed at the test position.
    - Make sure that loudspeaker is plugged into the **Left Speaker** socket of the SC.


Free Field Calibration: Step 5
Check the equipment setup as follows:
1. Loudspeaker is connected to the 'FF LEFT' / 'FF RIGHT' socket of the Stimulus Controller.
2. Microphone is connected to the 'CONTROL MIC' socket of the Stimulus Controller and placed at the reference point.
3. If an external amplifier is used, connect the amplifier input/output to the 'TO EXT AMP' and 'FROM EXT AMP' socket on the Stimulus Controller respectively.
4. If an external amplifier is used, set it to a nominal gain and recalibrate if it needs to be changed.
Click 'Next' to continue
< Back
Next >
Cancel

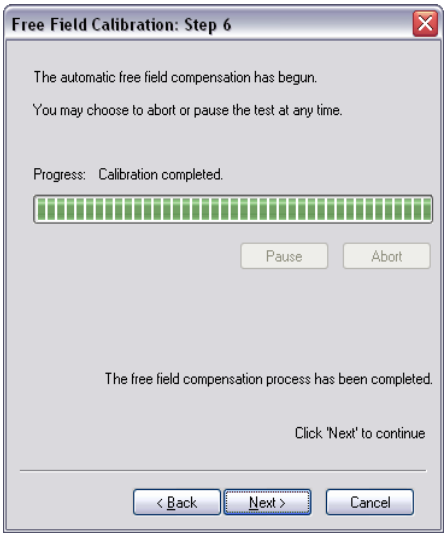
Equipment setup instructions

11. Click **Next** to proceed with calibration. A series of warble tones (from 125 Hz to 8 kHz in one-third octaves) will be presented through the loudspeaker. The signals will be recorded and measured by the microphone in order to obtain the frequency response of the free field environment.


Free Field Calibration: Step 6
The automatic free field compensation has begun.
You may choose to abort or pause the test at any time.
Progress: Obtaining free field frequency response...
Pause
Abort
< Back
Next >
Cancel

Automatic calibration in progress

- You may pause or abort the calibration process at any time.
- During the calibration process, the **Back** and **Next** buttons on the wizard will be disabled.
- If the system could not obtain a signal, or finds that the obtained frequency response exceeds ± 8 dB of the reference frequency but is still within ± 11 dB of it, a warning message will be displayed on-screen and you will be prompted to restart the automatic calibration process or to continue.
- After the first frequency sweep, the system will make automatic level adjustments as the second frequency sweep is presented in order to produce a (near) flat frequency response. The signals will again be recorded and measured by the microphone.
- Upon the completion of the second frequency sweep, the filtered (filter generated from obtained frequency response) ACA stimuli will be presented and recorded.
- The **Back** and **Next** buttons on the wizard will be enabled again after the automatic calibration process has completed.


Free Field Calibration: Step 6
The automatic free field compensation has begun.
You may choose to abort or pause the test at any time.
Progress: Calibration completed.
Pause
Abort
The free field compensation process has been completed.
Click 'Next' to continue
< Back
Next >
Cancel

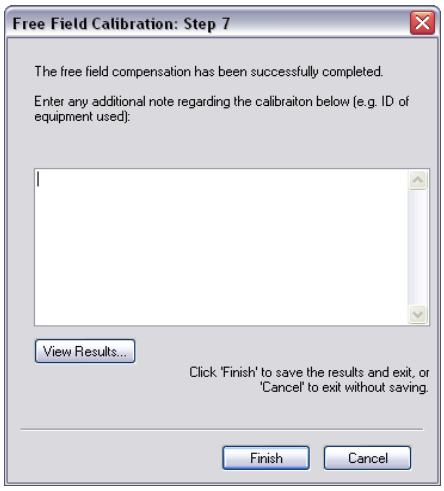
Automatic calibration completed

12. If the measured frequency response of the field exceeds ±10 dB, or if the adjusted frequency response still exceeds IEC 645-2 tolerances, you will be notified and asked whether or not you wish to retry the calibration.

    You may wish to view the preliminary calibration results before making the decision. If you choose to retry, the calibration process will be repeated, and all previous adjustments will be discarded.

    Before trying the calibration process again, You may wish to adjust the room setup (e.g. moving furniture around, moving the loudspeaker and test position further away from the walls) to improve the frequency response of the sound field.

13. Click **Next** to proceed to the next step in the calibration wizard.
14. Type any additional notes regarding the calibration (e.g. sound level meter used, name of the operators performing the calibration).
15. Click **Finish** to save the results and exit, or **Cancel** to discard the results and exit. **Unsuccessful calibration results cannot be saved.**

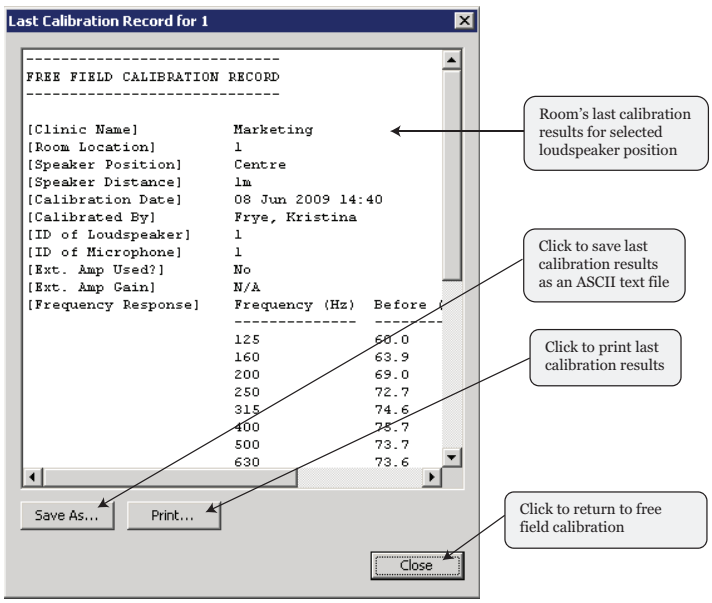

Free Field Calibration: Step 7
The free field compensation has been successfully completed.
Enter any additional note regarding the calibraiton below (e.g. ID of equipment used):
View Results...
Click 'Finish' to save the results and exit, or 'Cancel' to exit without saving.
Finish
Cancel

Comments in the Calibration Wizard

4.3 Calibration Results

You can view current calibration results, save them to a text file, or print a hardcopy.

1. Open the Calibration window by pressing CTRL+SHIFT+ALT+K.
2. Click the **Free Field** button. This will open the Free Field Calibration Wizard.
3. Click **View Results...** This will open the Last Calibration Record for My Room window.



- Click the **Save As...** button to save the calibration results into a text file.
- Click the **Print...** button to print the calibration results.

Tools & Utilities

In ACA, various administrative options and utility functions are provided for software housekeeping and purposes. These functions include:

- Administrative tools—user administration, user passwords, and setup location
- Database tools—database backup and restoration
- Utilities—quick impedance, ambient noise, and stimuli presentation level checks

5.1 Administrative Tools

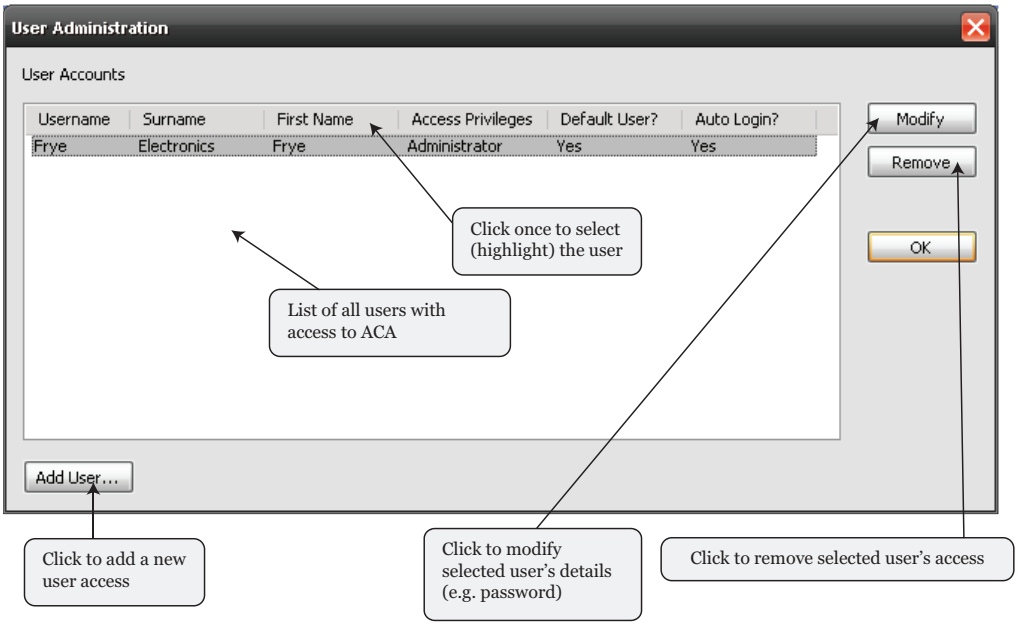
The tools described in this section include how to add a new user or motify an existing user, how to change the user password, and how to change the setup location for HEARLab.

5.1.1 User Administration

You must have HEARLab administrator privileges to perform the actions described in this section.

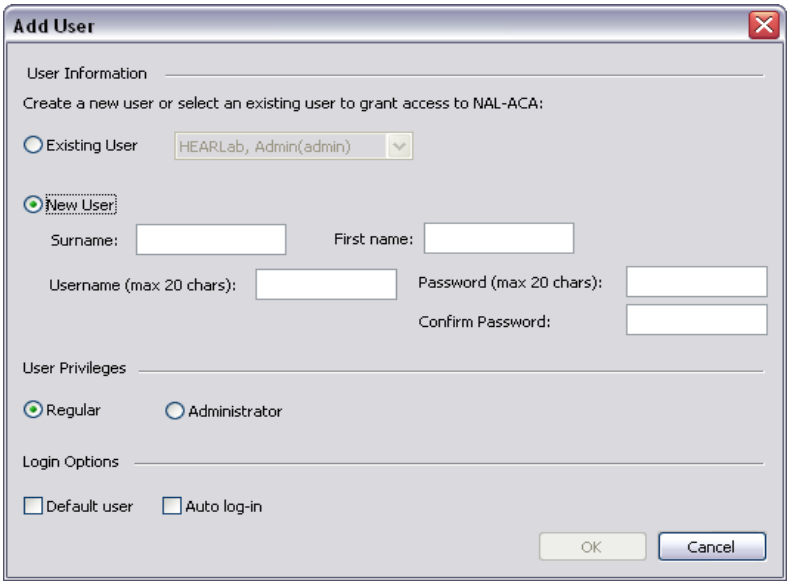
To Open the User Administration window

Open the **Tools menu** and select **User Administration…**



To Add a New User

Click the **Add User…** button in the User Administration window. This will open the Add User window.

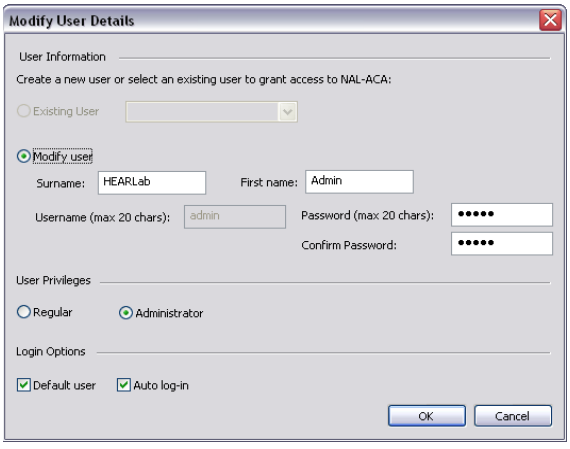


Add User window

- To create a new user, select **New User**. Enter the user's ID details, username and password, access privilege, and login options.
- To grant access to ACA for an existing user, select **Existing User** and use the list to select the user.
- Click **OK** to save the changes.

To Modify an Existing User

Open the User Administration window, select the existing user, and click **Modify**. The Modify User Details window will appear.



Modify User Details window

Modify the user's details as desired, then click **OK** to save the changes.

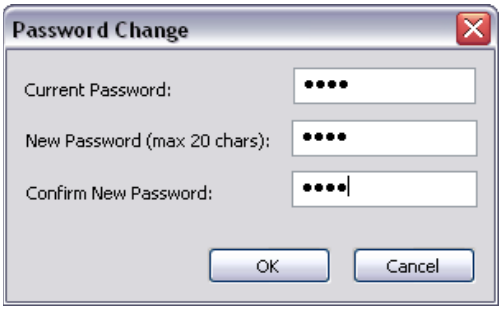
Delete a User

Open the User Administration window, select the existing user, and click **Remove**. The user will no longer have access to HEARLab ACA.

5.1.2 Changing Your Password

The current user may choose to change his/her password at anytime, and does not require administrator privileges to do so.

1. Open the **Tools** menu and select **Change My Password...** This will open the Password Change window.



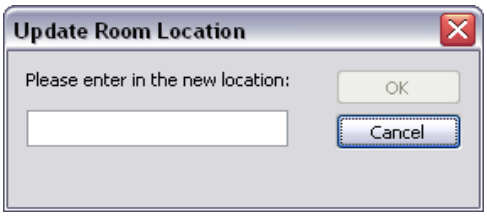
Password change window

2. Type in the current password, and then type in the new password twice in the fields indicated.
3. Click **OK** to save the new password.

5.1.3 Changing the Setup Location

The setup location of the HEARLab system is saved in the database in order to identify calibration results. Therefore if the system has been moved to another location, the setup location should be updated accordingly.

1. Open the **Tools** menu and select **Update Local Settings...** The Update Room Location window will be displayed.



2. Type the new setup location into the box.
3. Click **OK** to save the changes.

5.2 Database Backup and Restore

It is important to regularly backup the database to prevent the loss of clinical records in the case of a mishap. The database restore function allows the clinical records to be restored to a previous backed up version. Currently, the software does not provide a function for the merging of clinical records from different HEARLab setups.

5.2.1 Backing up the Database

1. Open the **Tools** menu, point at **Database Administration**, and select **Backup Database**. A Browse For Folder dialog will be displayed.

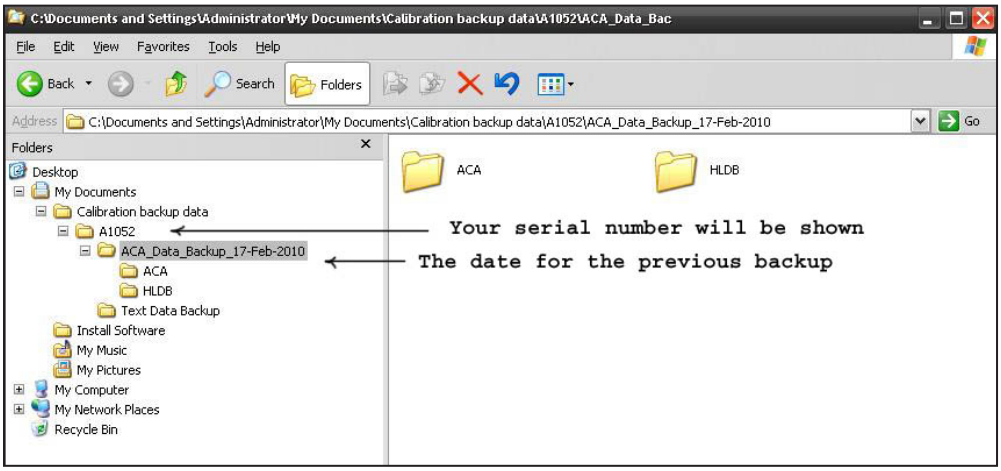
Select folder for database backup

2. Select the folder you want to use to store the database backup. A database backup directory containing the backed up data will be created in that folder. If you want to create a new folder, click **Make New Folder**.

3. Click **OK** to start the backup. A message box will be displayed to indicate the success / failure of the database backup.

5.2.2 Restoring the Database to a Previous Version

1. Open the **Tools** menu, point at **Database Administration**, and select **Restore Database**. A Browse For Folder dialog will be displayed.



Restore Database browser

2. Select the folder that contains the version of the database that you want to restore.

3. Click **OK** to start the restore. A message box will be displayed to indicate the success / failure of the database restore.

5.3 Utilities

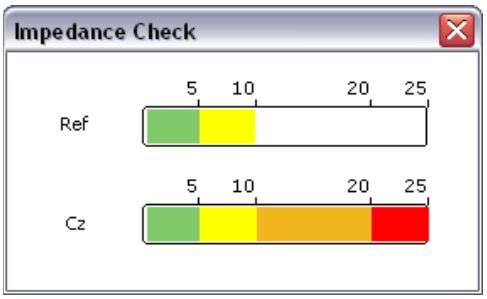
Several utility functions are provided in ACA to allow the user to perform quick checks on:

- Impedance of electrodes
- Output presentation levels of test stimuli
- Ambient noise measurement

5.3.1 Checking the Impedance

You may check the impedance at any time without needing to go through the client selection process.

- Open the **Tools** menu, point at **Utilities**, and select **Impedance Check...** This will display the Impedance Check window.



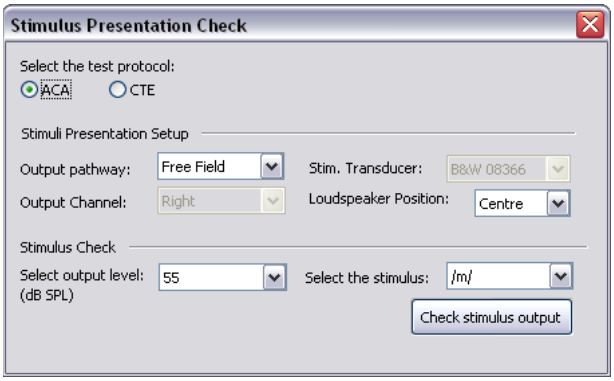
Impedance Check window

- The impedance of the reference and active electrodes will be automatically measured in 1 second intervals.
- Close this window when finished.

5.3.2 Checking the Stimuli Presentation Levels

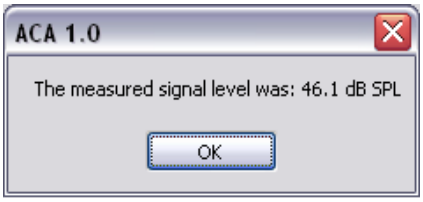
This function is used to check the output presentation levels of the ACA and CTE stimuli, thus ensuring the HEARLab calibration is still valid.

1. Open the **Tools** menu, point at **Utilities**, and select **Stimulus Presentation Level Check…**The Stimulus Presentation Check window will be displayed.
2. Specify whether the ACA or CTE stimuli are to be checked.
3. Specify the transducer you want to check by using the **Output Pathway** list.
   - Free Field (ACA)
   - Insert Earphone (CTE)
   - Bone conductor (CTE)



Stimulus Presentation Check window

4. If you are checking the free field calibration:
   - Place the control microphone at the reference test position such that the output can be measured.
   - Specify the loudspeaker position from which the stimuli are to be presented.
5. If you are checking the insert earphone or bone conductor calibrations:
   - Specify the **Output Channel** to test.
   - Specify the output transducer you are checking in the **Stim. Transducer** list.
6. Select the output level for the stimulus presentation.
7. Select the stimulus you wish to check.
8. Click **Check stimulus output**. The stimulus will be presented through the selected transducer at the specified presentation level. For ACA, the dB SPL output of the stimulus will be measured by the microphone and displayed in a message box.



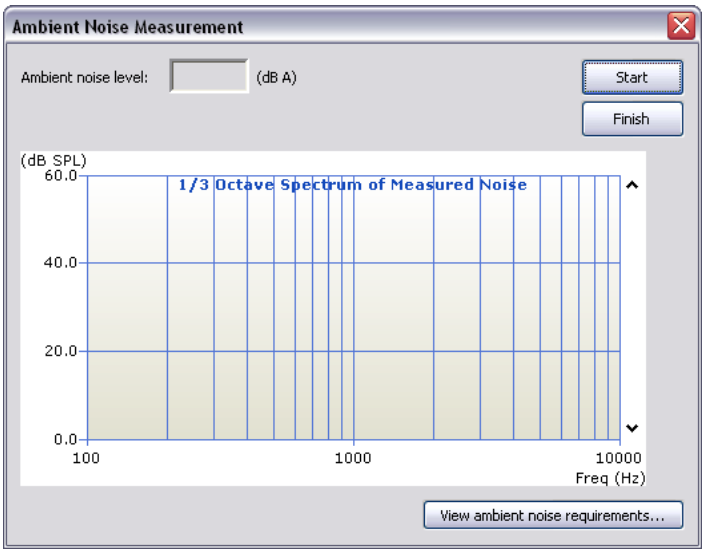
9. Click **Done** when you have finished checking the stimulus presentation levels.

5.3.3 Ambient Noise Measurement

Before performing an assessment or calibration, it is good practice to first measure the ambient noise of the room and check that the noise level is below the recommended levels. You can measure the ambient noise with the Ambient Noise Measurement window.

To perform this test, make sure the control microphone is connected to the Stimulus Controller. Position it at the test position (where the patient will be sitting).

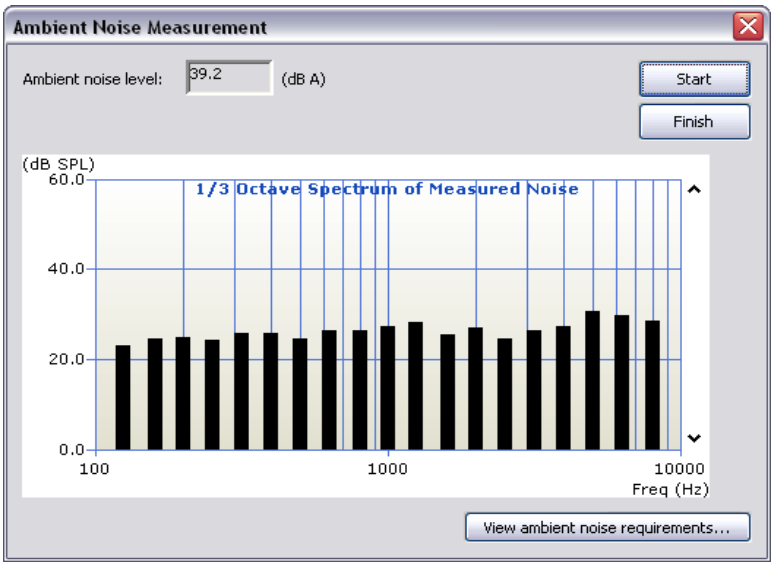
1. Open the **Tools menu**, point at **Utilities**, and select **Ambient Noise Check…** The Ambient Noise Measurement window will be displayed.



Ambient Noise Measurement window

2. Click **Start** to begin the ambient noise measurement. The microphone will record the ambient sounds, and the recording is filtered at 1/3 octave bands to produce the noise spectrum.

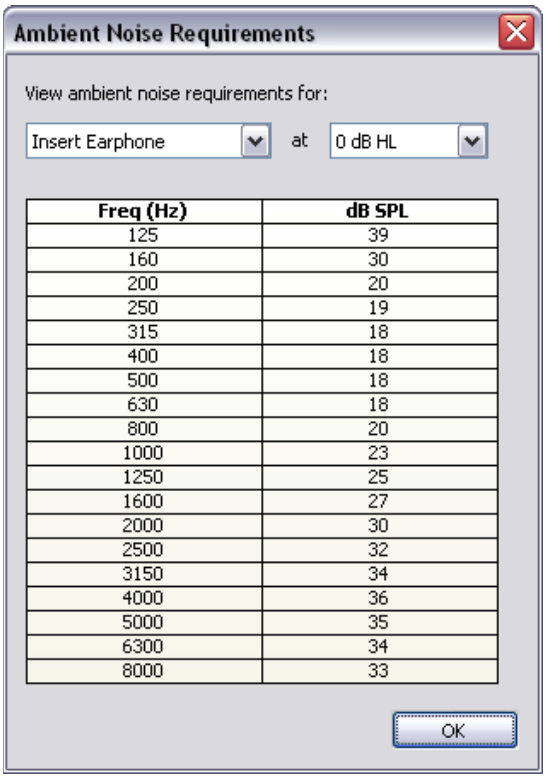
3. Once the analysis has been completed, the noise spectrum and the dB A level is updated.



Ambient Noise Measurement (completed) window

4. Click **View ambient noise requirements** to check the ISO 8253-1 requirements for for testing. A dialog with a table of the maximum permissible ambient sound pressure levels at each frequency for the selected transducer and test level is displayed.

5. Select the transducer (insert earphone or bone conductor) and the test level (in dB HL) in order to view the updated figures. In general, the ambient noise level should not exceed 35 dB A.



Freq (Hz)	dB SPL
125	39
160	30
200	20
250	19
315	18
400	18
500	18
630	18
800	20
1000	23
1250	25
1600	27
2000	30
2500	32
3150	34
4000	36
5000	35
6300	34
8000	33

ISO 8253-1 Ambient Noise Requirements

6. Click **Finish** to exit the test.

Reference

This chapter contains a list of all the toolbars and menu items in the HEARLab ACA software.

6.1 Toolbars

There are three toolbars in the ACA module:

- Main toolbar – Displayed in all windows
- Client toolbar – Displayed in the Client window
- Assessment toolbar – Displayed in the Impedance, Acquisition, and Results windows.

6.1.1 Main Toolbar

Click this button to access the Client window.

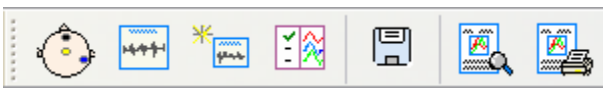
Click this button to specify a new assessment for the selected client.

6.1.2 Client Toolbar

Click this button to add a new client to the database

Click this button to search for an existing client OR to list all existing clients

6.1.3 Assessment Toolbar



Click this button to access the Impedance window.

Click this button to access the Acquisition window.

Click this button to specify a new run for the current assessment.

Click this button to view results for the current assessment.

Click this button to save assessment results to the database.

Click this button to access the assessment report's print preview.

Click this button to print the assessment report directly without previewing.

6.2 Menus

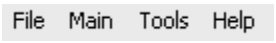
There are three menus bars available in HEARLab ACA.

- Main Menu Bar — available in all windows
- Client Menu Bar — available in the Client window
- Assessment Menu Bar — available in the Impedance, Acquisition, and Results windows

Note: The menu bar displayed at any one time is a combination of the main menu bar and one of the other two menus bars.

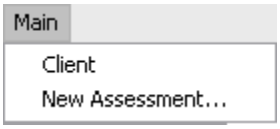
6.2.1 Main Menu Bar

File menu



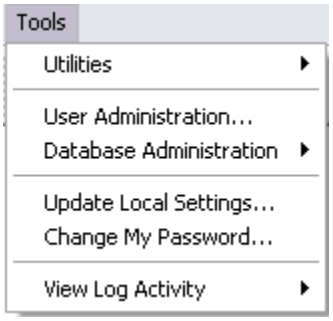
- **Switch User:** Log-in as a different user
- **Exit**: Exit ACA

Main menu



- **Client**: Access the Client window
- **New Assessment: S**pecify a new assessment for the selected client (this option is unavailable if no client has been selected)

Tools menu



- **Utilities**: View the submenu
- **User Administration…** View/edit registered users
- **Database Administration…** View the submenu
- **Update Local Settings…** Update the physical location of HEARLab (this information is used for calibration purposes).
- **Change My Password…** Modify your login password
- **View Log Activity…** View the submenu

Utilities Submenu

- *Impedance Check… Check electrode impedance without going through the client selection process*
- *Stimuli Presentation Level Check… Check the output level of the various ACA and CTE stimuli to ensure the calibration results are still valid*
- *Ambient Noise Check… Measure the ambient noise of the room*

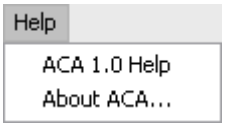
Database Administration Submenu

- *Backup Database: Perform database backup*
- *Restore Database: Perform database restor*

View Log Activity submenu

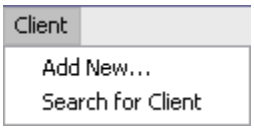
- Click **Module Log…** (or press **M** on the keyboard) to view the log activities for the module
- Click **System Log…** (or press **S** on the keyboard) to view the system log activities

Help menu



- **ACA 1.0 Help**: Access online help
- **About ACA…** View HEARLab ACA version information

6.2.2 Client Menu Bar



- **Add New…** Add a new client to the database
- **Search for Client**: Search for an existing client or to list all existing clients

6.2.3 Asssement Menu Bar

- **Impedance Check**: Access the Impedance window
- **Acquisition**: Access the Acquisition window
- **New Run…** Specify a new run for the current assessment
- **View Results**: View the current assessment's results
- **Save**: Save the results of the assessment to the database
- **Report**: View the submenu
- **View Settings**: View the submenu
- **View Client Info**: View current client information

Report submenu

- **Print Preview**: Access print preview of the assessment report
- **Print**: Print the assessment report directly without preview

View Settings submenu

- **Assessment:** View the detailed assessment settings of the loaded assessment
- **Run**: View the current run settings (applicable only for the active assessment)

6.3 Graph Scale changes

If it is desired to magnify or reduce the sensitivity of any of the graphs displaying the microvolt amplitudes of obtained cortical waveforms, in either the measurement or results screens, point and right click the computer mouse on one of the scale figures, such as "15.0 (uV)." A message box will appear and indicate to "change y-axis scale" or "default". If change is selected, a new box will appear and allow changes to the maximum and minimum values for the graph as well as the step size.

Overview of the ACA and CTE Modes

This chapter contains an overview of the Aided Cortical Assessment (ACA) and Cortical Tone Evaluation (CTE) modes.

7.1 ACA Mode

What is the ACA mode intended for?

The ACA mode allows speech stimuli to be presented in the free-field, and is an additional tool to assist in the evaluation of hearing aid fittings. It is intended to indicate whether speech sounds produce a cortical response in a person who has been fitted with hearing aids.

Important Note: Several studies have shown that a small proportion of people do not exhibit a strong CAEP even when the stimulus is far above their behavioural threshold. Clinical studies done with HEARLab ACA on children and on adults have also shown results in line with these studies. The implications are that an absent cortical response to a speech sound is not a certain indication that the test person (child or adult) cannot perceive that sound.

HEARLab is intended as an adjunct to the assessment of hearing, not as a replacement for other methods of hearing assessment.

For subjects fitted with cochlear implants, interference from some implant programs may render the recordings unsatisfactory. It is therefore not recommended to use HEARLab to assess subjects fitted with cochlear implants

ACA is most applicable in cases where the individual's pure tone hearing threshold levels are unknown or uncertain, making accurate hearing aid prescription and real ear evaluation difficult. The ACA module allows the audiologist to determine whether the hearing aid wearer has a CAEP response when presented with speech sounds of different frequency spectra at average conversational levels, with or without a hearing aid fitted. The most common scenarios for considering using the ACA mode are:

- The hearing aid wearer is not developmentally ready for behavioural aided (or unaided) hearing assessment
- The hearing aid wearer has disabilities in addition to hearing loss which make behavioural hearing testing unreliable, or impossible (e.g., children or adults with significant cognitive or motor impairments)
- The pattern of audiological results for the hearing aid wearer is complex, and there is great uncertainty about the pure tone audiogram on which the hearing aid prescription is based (e.g. infants who have evident otoacoustic emissions but an abnormal ABR, and may be affected by auditory neuropathy spectrum disorder).

What acoustic stimuli are available for presentation in ACA mode?

Three "natural" speech stimuli, /m/, /t/ and /g/ are available in the ACA mode. They are speech tokens extracted from recordings of running speech. They were chosen for their dominant energy spectrum in different frequency bands; /m/ for the low frequencies, /g/ for the mid frequencies and /t/ for the high frequencies. The aim is to gives some indication to the tester as to whether speech information of low-, mid- and high-frequency bands are independently detectable by the subject at the cortical level.

Recently the development of frequency transposition hearing aid devices allow the much higher frequency speech sounds, such as /s/, to be frequency shifted to a lower frequency band to allow those with no hearing in the higher frequencies to receive the transient information present in speech. The /s/ sound or phoneme has thus been added to the set of three described above. The presentation of this sound and the cortical analysis can be treated in the same way as is done with the other speech phonemes.

The presentation levels, 55 dB SPL, 65 dB SPL, 75 dB SPL, available in the ACA mode are closely indicative of the long-term rms level of continuous speech in which these sounds occur. Their durations are 30, 20, and 30 ms respectively, and they have dominant power in the bands 200 to 500 Hz, 800 to 1600 Hz, and 2000 to 8000 Hz respectively. The spectral energy of the speech stimuli is shown in Appendix B.

What presentation levels available for ACA mode?

Three presentation levels are available for each of the speech stimuli. These levels are:

- 55 dB SPL, representing speech at soft levels
- 65 dB SPL, representing normal (average conversational) speech levels and
- 75 dB SPL, representing speech at louder levels

The test parameters (stimulus type and presentation level) can be selected by the tester prior to each new test run. Typically, the tester may commence an assessment with hearing aids for the three speech sounds at 65 dBSPL. If the cortical response is present, testing at 55 dBSPL may be desirable. If the cortical response is not present, the tester may choose to go on and test at 75 dBSPL.

NOTE: The ACA mode is not intended for frequency-specific threshold testing. The CTE mode should be used for evaluating the audibility of highly-frequency specific tones.

Can ACA testing be performed monaurally?

Masking is not available for testing in ACA mode. However, the non-test ear may be blocked with an earplug (e.g. foam EAR plug). For aided evaluation, if monaural results are desired the hearing aid in the non-test ear can be left in-situ but switched off.

7.2 CTE Mode

What is CTE mode intended for?

The CTE test uses tone bursts to determine at what levels these frequency specific tones are audible to the test person. This assessment can be used for estimating the hearing threshold levels of hearing-impaired adults without requiring the active participation of the person

being tested. The relationship between the estimates of hearing threshold obtained on the basis of the CAEPs detected by HEARLab, and behaviorally measured hearing thresholds has so far been established only for adults aged 43 to 89 (mean age 71 years).

Important Note: Several studies have shown that a small proportion of people do not exhibit a strong CAEP even when the stimulus is audible. Clinical studies done with CTE on adults have also shown results in line with these studies. The implications are that-Hearing thresholds estimated on the basis of the presence and absence of cortical responses will significantly over-estimate behavioural threshold for a small proportion of adults. The accuracy of estimates in children is unknown and HEARLab is not intended for this purpose. HEARLab is intended as an adjunct to the assessment of hearing, not as a replacement for other methods of hearing assessment.

What acoustic stimuli are available for presentation in CTE mode?

There is a choice of six tone-burst frequencies in the CTE mode. The envelope of these tone-bursts comprises a rise time and a fall time of 10 ms with a plateau of 30 ms. The duration of these tone-bursts is equivalent to 40 ms. The tone-burst frequencies available are 500, 1000, 1500, 2000, 3000 and 4000 Hz. The calibration procedure employs a continuous tone that has the same peak level as the tone-burst stimuli used during the cortical testing. To compensate for the short duration of the tone bursts, the CTE mode automatically applies a 6 dB correction to the levels determined in the continuous tone calibration.

Choice of transducer and test levels in CTE mode

In the CTE mode the acoustic stimulus can be presented by air conduction (via an insert earphone) or by bone conduction. The choice of test levels available is:

Insert phone: -10 dB HL to 110 dB HL (5 dB step size)

Bone conductor: -10dB HL to the maximum levels specified below (5 dB step size):

Center Frequency (Hz)	Max dB HL
500	60
1000	70
1500	70
2000	70
3000	70
4000	60

Masking for CTE testing

When testing with insert phones, masking is available for the non-test ear. The masking signal is a narrow band noise centered at the test frequency. Narrow band noise, centred at the test frequency, is routinely and effectively applied in conventional audiometry (Hall, 2007; Hyde, 1997) and is appropriate for cortical testing with tone burst stimuli delivered via air or bone conduction (Goldstein et al, 1999). The level of masking applied should follow normal audiometric rules (Reid & Thornton, 1983). Given the increased inter-aural attenuation offered by insert earphones, masking to the NTE may not be needed for stimu-

lus levels if the TE level ≤70 dB HL. Inter-aural attenuation for insert earphones may be as great as 60 dB (Hall, ibid). Where masking is indicated, the CTE mode offers a masking range of +10 to -30 dB (relative to the stimulus presentation level). Testers should be aware that with extreme stimulus presentation levels (e.g. 110 dB in the test ear) the contralateral masking may be 80 dB or more which may present the possibility of over-masking.

7.3 Notes on the Use of HEARLab ACA

7.3.1 Monitoring of test participant state

The state of alertness of the test participant is critical in cortical testing. This applies equally when us-ing the HEARLab device in either the ACA or CTE mode. Sleep is known to affect the amplitude of cortical responses, and the EEG background noise (Hall, 2007). There is evidence that attention af-fects response amplitude and waveform shape, particularly near behavioral threshold. When CAEP morphology changes because of alterations in alertness state of the subject, the averaged waveform will accumulate different shapes of cortical responses. This will negatively affect the end result. It is therefore recommended to keep the subject in a similar state during testing.

It is also important to maintain the most favourable signal to noise ratio (SNR) conditions possible, and the test participant themselves can be a source of noise. Vocalisation can be a significant acoustic noise source (usually when testing young children). Physical movements (voluntary or involuntary), neck muscle tension, and chewing can also introduce unwanted electrophysiological noise which can be much higher in amplitude than cortical responses. The electrical activities of these muscular ac-tions and associated nerve potentials are much closer to the electrodes than the cortical potentials that originate more remotely. These signals are also picked up as noise by the electrodes at higher intensi-ties than cortical potentials. To reduce the effect of high amplitude noise in the recording, HEARLab rejects any epoch which contain a sample value either equal or greater than +150 μV or equal or less than -150 μV. Even with artifact rejection, which only removes extreme values in the EEG, a traffic light system is desirable, as the range of possible noise levels originating from subjects is large. For example, it is possible that a subject generates a continuous elevated background noise without ex-tremes when compared to another subject who is much quieter. In both cases the artifact rejection will not filter away these types of noise.

It is recommended that cortical testing is carried out in a quiet, comfortable test environment. Ideally, the test participant should be awake and alert, yet physically as relaxed as possible, and preferably with the head looking straight ahead and supported from behind (e.g. by a parent's chest in the case of an infant). The tester needs to monitor the test participant constantly to be aware of any changes in their level of alertness and/or physical state. To ensure that adults and older children remain in an ideal state, allowing them to watch a silent DVD of interest to them is a good technique. When test-ing younger children/infants, a trained test assistant can be an advantage in monitoring the child's state, keeping the child as quiet and content as possible, and keeping the child looking straight ahead. A parent or caregiver may also be able to assist in this respect. Refer Appendix A for more detailed pediatric distraction techniques.

As well as observing the test participant, the tester may be alerted to problems with the participant's state by noting changes in the EEG and/or a high epoch reject rate (refer also to the following section regarding the "noise indicator").

If test conditions become unfavorable for any reason, the tester has the option of pausing the record-ing and resuming the test as soon as favorable conditions are restored, or truncating the test and re-starting it.

7.3.2 Interpretation of results

HEARLab calculates and displays the averaged response waveforms. The tester can review these waveforms and mark key features (i.e., peak amplitudes and latencies) before saving and printing re-ports. HEARLab also provides a detection statistic and a noise indicator to assist the tester in deter-mining whether the stimulus produces a CAEP response in the participant. These indicators are aimed at improving test sensitivity, and enabling meaningful interpretation of results to be achieved, even by testers with limited experienced in interpreting cortical response waveforms.

7.3.3 Noise Indicator

The 'Residual Noise Level' indicator shows how noisy the recording has been. The indicator esti-mates the noise amplitude that is left in the averaged epoch. The residual noise decreases in value as the number of epochs increase provided the state of the person being tested remains constant. This is similar to the decreasing noise visible in the visual representation of the grand average waveform as more epochs are averaged during a recording.

For infants in a relaxed state, residual noise voltages are typically about 3.4 μV after 100 epochs, so the traffic light has been set to turn green for residual noise less than 3.2 μV and to turn red for residu-al noise greater than 3.6 μV.

7.3.4 Detection Statistics

HEARLab ACA employs statistical techniques to determine whether a CAEP is actually present. The analysis result is expressed as a p-value. The detection p-value is the probability of obtaining data as or more extreme than what was observed, under the assumption that there was no cortical response. A detection p-value < 0.05 is often taken to represent a significant response. Loosely stated, the lower the p-value that is obtained, the greater is the probability that a CAEP is present.

Guide on use of the noise indicator and the detection statistics

HEARLab ACA calculates and displays the average waveforms and probability values, without any need for off-line processing by the tester. The tester can decide whether a stimulus produces a CAEP response in the test participant, based on the p-value. Research conducted by NAL has shown that this technique is as sensitive as (and sometimes more sensitive than) visual interpretation of the waveforms by an experienced tester. Note, however, that a high residual noise (red or yellow) should caution against making a decision if the p-value is not significant. That is, if the residual noise level is high, it can NOT be concluded that the test sound hasn't produced a response, just because the p-value is greater than 0.05. The noise may in fact be masking the presence of an actual cortical re-sponse.

If the test participant starts the test run in a restless state (resulting in a large amplitude on the contin-uous EEG record, and a high residual noise in the traffic light indi-

cator) but subsequently settles to a more desirable state, it is possible that a good quality averaged response will be obtained more quick-ly if the test is restarted than if the test is continued. This is because the large number of noisy re-sponses collect-ed early in the test run will contribute unduly to the overall response.

Deciding on the number of epochs to collect for each test run

The greater the number of accepted epochs in a test run, the lower the noise in the resulting average waveform is likely to be. However, the number of epochs impacts on the test time and so is a consid-eration, particularly if the tester wishes to conduct a large number of runs.

During a test run, acquisition of cortical responses stops automatically when the number of accepted epochs, preset by tester, is reached for all stimuli selected for that test run. If an infant is tested, it is recommended to preset at least 200 epochs to be accepted. For adults, this value can be reduced to 100.

In any case, it is imperative to not stop the recording earlier before the system stops automatically at the predefined number of epochs. Then, one needs to evaluate the presence of a cortical response ($p < 0.05$ for present and $p > 0.05$ for not present). Remember that adopting a p-value criterion of 0.05 is equivalent to accepting that 1 time in 20, a "significant" response will appear to be present even when there is in fact no response present. Only in the special case that a p-value is smaller than 0.001 (indi-cated in HEARLab by $p=0.000$), it is statistically allowed to stop the recording earlier.

Please note that in the ACA mode it is possible to have two or more stimuli selected in a single test run. If the preset number of accepted epochs is reached first for one of the stimuli, further presenta-tion of this stimulus automatically ceases. The remaining stimuli continue to be presented until the preset number is reached in each case.

It should also be noted that as stimuli are presented in blocks of 25 the stop criteria can occasionally be exceeded, if the required number is achieved part-way through a presentation block.

7.3.5 Cortical Latencies

The averaged CAEP waveforms of adults typically exhibit 2 positive and a negative peak that are labeled as P1, N1 and P2. In infants, only one positive peak is present. The negative peak, and second positive peak, develop with increasing age. HEARLab indicates the typical range of latencies for the single positive peak, when the age is less than 15 years (calculated from the date of birth entered in the client details screen). The range is a function of age and is calculated from a regression equation based on previous research (see scientific background to the CAEP section).

HEARLab indicates the typical range of latencies for subjects older than 15 years according to the following ranges

Peak	P1	N1	P2
Latency range (msec)	40-100	75-150	150-300

The age-dependent typical ranges for latency should be considered as guidelines only.

The significance of an individual having latencies falling outside the normal range has not been extensively investigated. There is, however, evidence that:

- Auditory deprivation during the first months or years of life is likely to cause delayed latency when sound is first experienced, although latency is likely to progress towards and eventually reach normal latencies if auditory stimulation (via cochlear implantation) occurs before the age of 3.5 years and may reach the normal latency range if stimulation occurs before the age of 7 years (Sharma, Dorman & Spahr, 2002).
- Longer latencies are associated with poorer speech perception for wearers of cochlear implants (Sharma, 2008).

Scientific Background of CAEP

This chapter contains information on the scientific principals of Cortical Auditory Evoked Potentials (CAEPs).

CAEPs have been recorded both in clinical and research settings for decades. As early as the 1960s, studies have reported the application of the CAEP technique (Coles & Mason, 1984; Cone-Wesson & Wunderlich, 2003; Davis, 1965; Hyde et al., 1986; Rickards et al., 1996).

8.1 Physiological Mechanisms of the CAEP

The CAEPs of interest for HEARLab are the P1, N1 and P2 responses. These responses are assumed to be generated at different levels of the auditory cortex, which is a complex network of neural cells and fibres. The physiological mechanisms of the CAEP are complex and have been the subject of much study and debate (Hall, 2007). Much of what is understood regarding the mechanisms of cortical processes in humans has been inferred from animal studies. Several comprehensive texts can provide the reader with an overview of this debate (e.g. Burkard et al., 2007, Hall, ibid). Eggermont (in Burkard et al, ibid) describes the auditory cortex as a hierarchical structure, with three broad subdivisions, referred to as the primary, secondary and tertiary cortex. The cortex as a whole is organized in terms of six laminae, or layers, parallel to the folded cortex surface (Katz, 1985).

The origins of the voltages observed on the scalp can be understood as follows (Burkard et al., ibid). The auditory cortex receives excitatory input from specific auditory areas in the thalamus. Axons from thalamic neurons communicate synaptically with the long fibre-like dendrites of cortical neurons. These dendrites run perpendicular to the cortical laminae and cortical outer surface. The inflow of positive ions that occurs following excitation at a synapse creates a positive-going post-synaptic potential within the dendrite (i.e. depolarization). As a result of the inflow, the extracellular environment local to the inflow position becomes more negative. Extra-cellular current then flows throughout the cortex from positively to negatively charged regions to equalize the extra-cellular potential throughout the cortex. If the synaptic excitation (and hence depolarization) happens relatively deep below the cortical surface, for instance at layer IV, the extra-cellular currents predominantly flow from superficial layers to the deeper layers. Positions on the scalp closest to the superficial layer therefore acquire a positive voltage relative to positions on the scalp closer to the deeper layers. Because the surface of the auditory cortex lies mostly within the Sylvian fissure, most dendritic fibers run tangential to the scalp. Consequently the upper half of the scalp, including the vertex, becomes positive relative to the lower half of the scalp, including the mastoid. This is thought to be the origin of the P1 peak, and to be one of the origins of the P2 peak. Conversely, if the original synaptic excitation and consequent depolarization occur in a more superficial layer (e.g. layer II), then the extra-cellular current flows from deeper to more superficial layers, and the vertex will become negative with respect to the mastoid. This is thought to be the origin of the N1 response. As dendrites and synaptic connections do not form in the superficial layers until after about five years of age, this is consistent with the absence of an N1 response in infants (Kraus, 1993).

Amplitudes of auditory evoked potentials, including the CAEP, are thought to be affected by the summation of contributions from multiple sources that may have opposite polarities and hence have partially cancelling effects (Burkard et al., ibid).

Multiple mechanisms contribute to the latency of the cortical responses, including the cochlear travelling wave (which is more relevant to the low frequency components) and the time taken for the neural activity to travel through the brainstem to the cortex. However, the latencies of the P1 peak (60 ms in adults), N1 peak (100 ms in adults) and the P2 peak (180 ms in adults) are far too long to be fully accounted for by these factors, particularly the latter two peaks. The additional delay may be accounted for by neural activity forming synchronised circuits between different layers and areas of cortex and between the cortex and thalamus (Burkard et al., ibid). EEG activity in the cortex can be detected because the dendrites predominantly run in "vertical" columns (i.e. at right angles to the cortical surface). Because they are parallel, the extra-cellular currents they induce sum coherently, and hence can be detected at a distance, on the scalp. Conversely, dendrites in the thalamus are not arranged in a parallel structure, so the activity cannot be detected at the head surface, perhaps accounting for the periods between the peaks of the CAEP waveform.

8.2 Characteristics of the CAEP

The major components of the CAEP change substantially over the first 14-16 years of life (Hyde, 1997; Pasman et al, 1999; Rotteveel et al, 1986). These changes are not fully understood (Kushnerenko et al, 2002; Wunderlich and Cone-Wesson, 2006), however, it is believed they reflect underlying developmental changes in the response generators, such as increased speed of propagation arising from increased axon myelination and from maturation of intra- and inter-hemispheric connections throughout the cortex (Cunningham et al, 2000; Eggermont and Ponton, 2003). The newborn infant cortical response is dominated by a prominent positive peak at 200 to 300 ms when recorded at the midline (Kurtzberg, 1989; Sharma, Dorman, & Spahr, 2002; Stapells & Kurtzberg, 1991). By adult years (i.e., over 20 years), the dominant component is a negative peak (N1 at 80 – 120 ms) that is preceded and followed by positive components (i.e., P1 at 50 to 70 ms, and P2 at 150 – 200 ms) (Davis, 1965; Ponton et al., 2000).

Response amplitude, latency and wave morphology also vary substantially between and within subjects due to a number of other factors, such as:

a. varying levels of alertness (Hyde, 1997; Wunderlich & Cone-Wesson, 2006),
b. inadequate signal to noise ratio, due to an inadequate numbers of epochs within the averaged response (Molfese, 1978)
c. excessive levels of background noise from a participant's restless state (Hyde, 1994).

CAEPs in young children can show even more variability than those of adults because of increased electrophysiological noise brought about by movement of the electrode-skin interface when physical movement occurs, or sudden alterations of psychological state (Hyde, ibid).

8.3 Clinical Application of the CAEP

In the past, the main application of the CAEP technique has been in estimating auditory threshold to frequency specific stimuli in adults who are unable, or unwilling, to participate in normal behavioral testing (Coles & Mason, 1984; Cone-Wesson & Wunderlich, 2003; Davis, 1965; Hyde et al, 1986; Rickards et al, 1996). In particular thresholds inferred from CAEP responses are valuable in evaluating claims for hearing loss in worker's compensation cases.

CAEPs have not been routinely used as a threshold estimation technique for infants, given the availability and popularity of alternative techniques such as Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR) (Purdy et al, 2005). It is well established that Cortical Auditory Evoked Potentials (CAEPs) can be reliably recorded in infants, and as early as 1967, CAEPs were explored as a technique in evaluating hearing aid fittings for children (Rapin & Graziani, 1967). Carter et al. (2010) cite several more contemporary references to the recording of CAEPs in infants (Cone-Wesson et al, 2003; Kurtzberg, 1989; Steinschneider, 1992). Purdy et al. (ibid) also reports that the developmental time course of the CAEP in infants has been investigated extensively (e.g. Kurtzberg et al., 1984; Novak et al., 1989; Ponton et al., 1996). There has been a renewed interest in the clinical applicability of CAEPs to the infant population during the early years of the 21st century, stimulated by the need to verify hearing aid fittings for infants referred early in life by newborn hearing screening programs. CAEP is particularly appealing in this context, as in contrast to other electrophysiological techniques (ABR and ASSR) The recording of CAEPs verifies the detection of the speech stimuli at the highest level of the auditory system.

While the relationship between CAEPs and speech perception is yet to be fully documented, there is clear evidence indicating that CAEPs relate well to behavioural measures of auditory perception (Purdy et al., ibid). For example:

i. Studies have investigated the effects of changes in speech stimulus parameters, e.g. voice onset time and place of articulation (e.g., Tremblay et al., 2003).

ii. Changes in CAEP as a result of listening training (that has resulted in improved speech discrimination, confirmed behaviourally) have been documented (Tremblay & Kraus, 2002).

iii. A clear relationship between speech perception and the presence of CAEP has been demonstrated in children diagnosed with auditory neuropathy/dys-synchrony (Rance et al., 2002).

iv. Several authors report on the recording of CAEPs to verify the audibility of stimuli for infants fitted with hearing aids (Cone-Wesson et al., 2003; Gravel et al., 1989).

v. A statistically significant relationship has been shown to exist between the observations of parents regarding their child's auditory function in everyday situations (as recorded using the Parent's Evaluation of Aural/Oral Performance in Children) and the presence of CAEPs (Golding et al., 2007).

vi. The latency of CAEPs in children who have received cochlear implants has been shown to be closely associated with the speech perception ability of those children (Sharma, 2008).

8.4 Relationship of CAEP to audibility behavioral thresholds

This section describes research studies performed to verify the presence (or absence) of the CAEP when a stimulus is presented above (a positive 'sensation level') or below (a negative 'sensation level') the subject's behavioral threshold. Stimuli are presented using HEARLab ACA (in adults and children) and CTE (in adults only).

8.4.1 Measuring adults with the ACA module

In Carter et al. (2012), HEARLab ACA was used to assess the audibility CAEP presence of to speech sounds for 10 adults with mild–severe hearing loss wearing hearing aids. The sounds /m/, /t/ and /g/, filtered in various ways (high-frequency emphasized, no filtering, and low-frequency emphasized) were presented through a loudspeaker. The behavioral thresholds for each of the nine sounds were measured for each participant. The sounds were then presented by HEARLab ACA at sound pressure levels of 40, 50, and 60 dB SPL, the cortical responses were registered on HEARLab ACA, and their statistical significance was calculated by HEARLab ACA. (HEARLab ACA normally presents levels of 55, 65 and 75 dB SPL, chosen to represent soft, average and loud speech respectively. Levels 15 dB lower than the levels normally produced by HEARLab ACA were used in this experiment to increase the proportion of sounds below behavioral threshold, so that the relationship between audibility sensation level and cortical responses could more critically be examined.) This attenuation and the filtering were achieved with equipment interposed between the HEARLab System speaker output socket and the speaker itself.

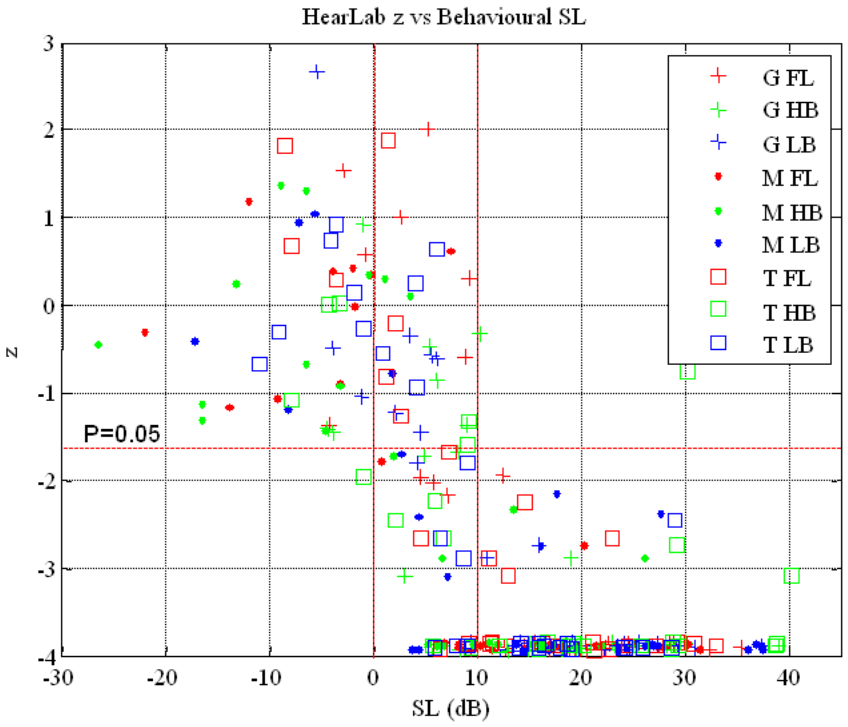


Figure 8.4.1: z-scores versus behavioral sensational level for HearLab data obtained on adults wearing hearing aids, for the sounds /g/, /t/ and /m/ under 3 filtering conditions (flat, high boost, and low boost)

Figure 8.4.1 shows the p-value displayed on the HEARLab ACA screen, transformed to z-scores to linearize the scale, versus the sensation level (relative to behavioral threshold) of each stimulus. A p-value of 0.05 transforms to a z-score of -1.64, as indicated by the dotted horizontal line. For sounds below threshold (i.e. SL<0), there was only 1 case out of 45 for which HEARLab ACA indicated a significant response. (At the p=0.05 significance level, 2 such cases would be expected by chance alone.) For sounds more than 10 dB above threshold, there were only 2 cases out of 147 for which HEARLab ACA did not indicate a significant response, one of which was for a sensation level of 10.5 dB. As sensation levels increase from 0 to 10 dB, there is a progression towards significance, with a total of 43 significant responses out of 69 cases within this range. The many results with a z-score of -4 correspond to the cases where the certainty of a significant response was so high, HearLab indicated a p-value of 0.0000.

For adults with mild to severe sensorineural hearing loss, listening to speech via their hearing aids, HEARLab ACA very reliably distinguishes cases where the sound is below behavioral threshold from cases where the sound is more than 10 dB above behavioral threshold. See Section 8.4.3 for a study involving HEARLab ACA measured with children.

8.4.2 Measuring adults with the CTE module

In a study populated by 34 adults with a wide range of hearing losses, the correction factors (and their accuracy) have been determined that should be applied to cortical auditory evoked potential (CAEP) thresholds for tone-bursts to estimate behavioral thresholds for pure-tones. Short acoustic stimuli with frequencies of 500, 1000, 2000, and 4000 Hz were presented to the subject using insert phones (Etymotic Research ER-3A). Behavioral pure-tone thresholds were determined in 2 dB steps by connecting these insert phones to a standard audiometer which provided pure-tone stimuli. When objective thresholds through CAEPs were measured, the insert phones were connected to HEARLab and the Cortical Tone Evaluation (CTE) routine was used. This procedure generated tone-bursts in 5 dB steps. The lowest intensity which generated a CAEP, was defined as the objective CAEP threshold.

Figure 8.4.2 shows the histogram of the differences between tone-burst CAEP and pure-tone behavioral thresholds. Correction factors per audiometric frequency (mean ± SD, in dB) are 3.36 ± 6.78, 4.22 ± 9.09, 5.87 ± 14.99, and 4.67 ± 12.95 for 0.5, 1, 2, and 4 kHz respectively. These correction factors should be subtracted from the threshold obtained by HEARLab CTE. They indicate that for the average hearing-impaired person the applied tone-burst is audiblethe actual behavioral threshold is at a level slightly below that at which a cortical response can be recorded. For about 7% of the population (indicated by the small bars on the right hand side of the histogram in Figure 8.4.2), sounds need to be rather far (20 dB or more) above their behavioral threshold to record a cortical response. This means that one should not conclude with certainty that a sound is inaudible below a for a subject's behavioral threshold if no cortical response is detected.

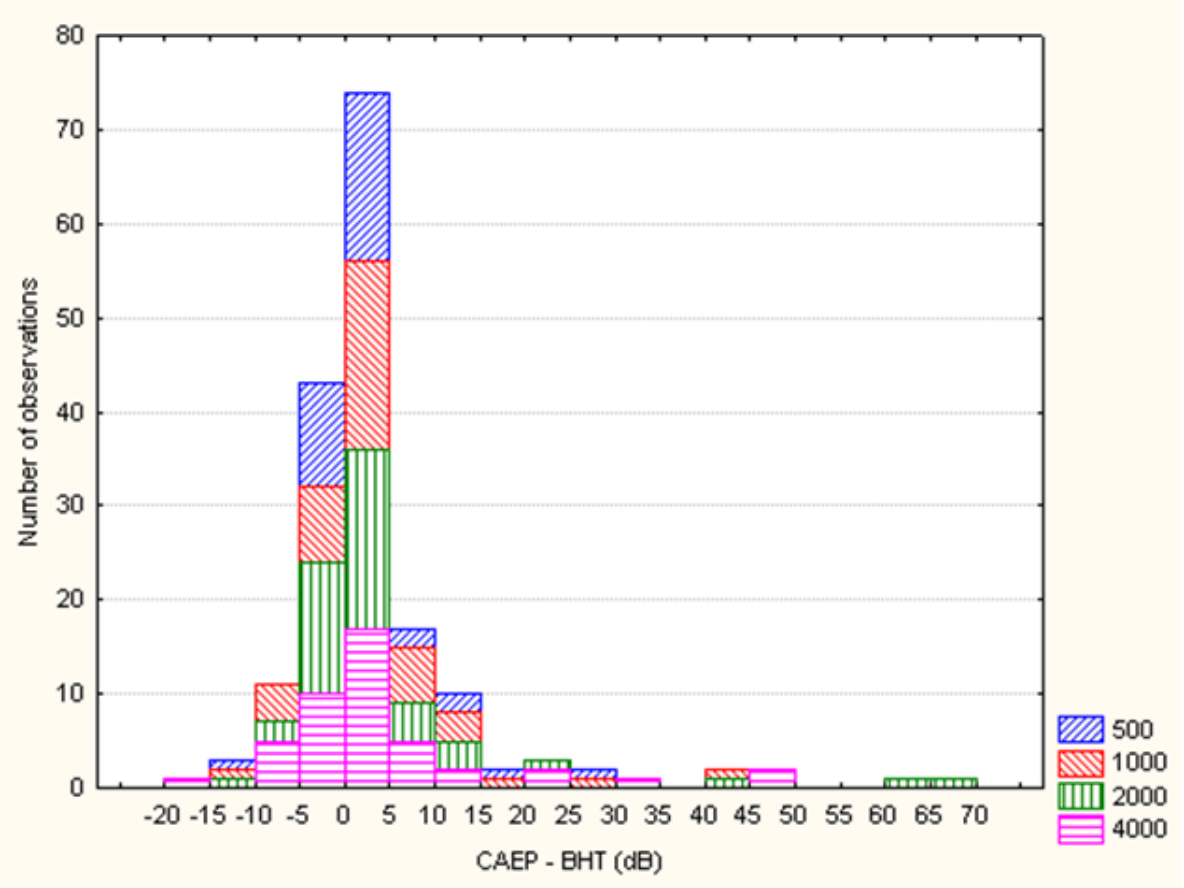


Figure 8.4.2: Histogram of the differences between HEARLab tone-burst CAEP thresholds and audiometer pure-tone behavioral thresholds for four audiometric frequencies (0.5, 1, 2, and 4 kHz).

8.4.3 Measuring children with the ACA module

In Van Dun et al. (2012), incorporating 25 hearing-impaired infants between 8 and 30 months of age, the sensitivity was determined with which cortical responses can be detected in infants of this age range. The tests were conducted either aided or unaided, depending on the degree of hearing loss of the infants. Infants with a hearing loss greater than 50 dB HL were assigned to the `aided condition' group. In the aided group, both hearing aids were used on the participant's prescribed settings. The experiment was divided in two parts. Two out of three speech stimuli /m/, /g/, and /t/ were tested. First, the behavioral thresholds for speech sounds were measured using Visual Reinforcement Observation Audiometry (VROA) in free field. Only thresholds within the range 35 dB SPL to 85 dB SPL were measured. Second, for the assessment of cortical responses with speech sounds, stimuli were presented in free field using HEARLab ACA. Speech stimuli were initially presented at 65 dB SPL. If responses to both stimuli were present, the intensity for both stimuli were lowered to 55 dB SPL. Otherwise, the intensity was increased to 75 dB SPL. If the infant was still in a calm and awake state, stimuli were presented at 75 and 55 dB SPL respectively.

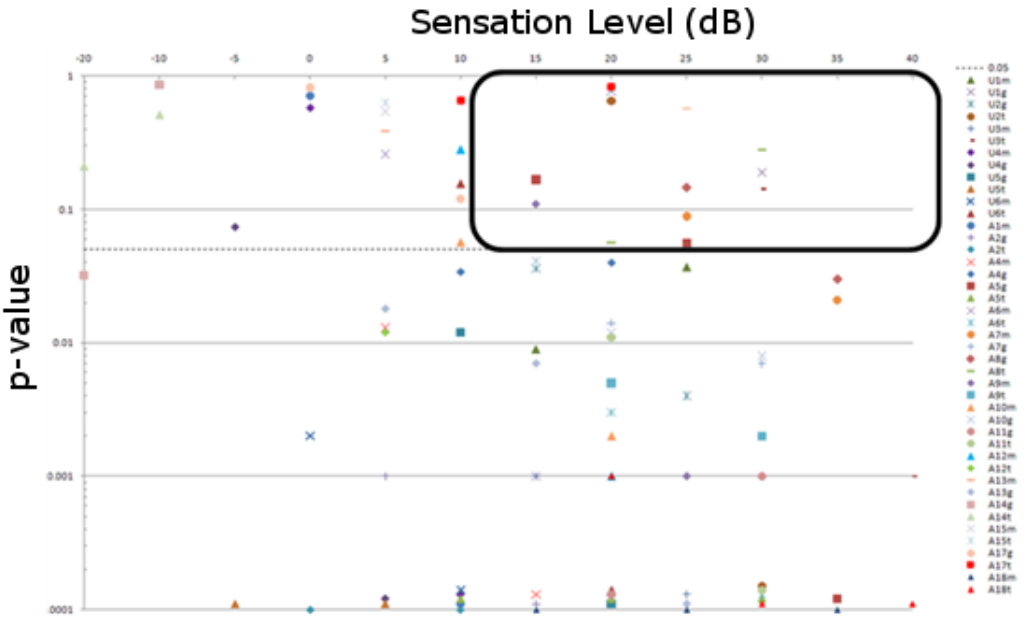


Figure 8.4.3: p-value versus behavioral sensation level for HEARLab data obtained from hearing-impaired infants, for the sounds /m/, /g/, and /t/. The black box covers 23% of the data points that were obtained from sensation levels exceeding 10 dB SL, but did not evoke a cortical response. Conversely, 77% of the responses evoked by >10 dB SL stimuli were significantly present.

Figure 8.4.3 shows a scatterplot focusing on the p-values of individual subjects, plotted with respect to sensation level (dB SL). Similar data points represent the same speech sound presented to the same subject, at different intensities. Values shown on the HEARLab ACA screen as $p = 0.000$ have been plotted at $p = 0.0001$, plus a small random offset to avoid overlapped points. There is a strong trend of decreasing p-values with increasing sensation level for most individual subjects. It is observed that several data points are non-significant, while sensation levels are positive. In particular, the black box covers 23% of the data points that were obtained from sensation levels exceeding 10 dB SL, but did not evoke a cortical response. Conversely, the HEARLab device detects cortical auditory evoked potentials in 72 % (confidence interval range 57 to 84 %) and 77 % (confidence interval range 60 to 90 %) for sensation levels of > 0 and > 10 dB SL respectively. This result is applicable to infants of 8 to 30 months of age, irrespective of being tested aided or unaided.

The implications of these relationships concerning the assessment of audibility whether a presented free field stimulus is above or below the subject's (un)aided behavioral threshold, are the following. First, consider the situation where a cortical response is present ($p < 0.05$) in response to a sound at a conversational level. This result provides some confidence that the tested level is above the infant's (un)aided behavioral thresholdinfant is perceiving that sound at the level tested. The smaller the p-value indicated by HEARLab ACA, the less likely it is that the displayed waveform is the result of random electrical activity. As the p-level is displayed by HEARLab ACA, the clinician can directly take this probability into account in deciding how much confidence to place on the finding when the clinician combines this piece of information with other information available to the clinician about the child. As it was relatively common (Figure 8.4.3) to find probability levels of 0.01 or less, often much less, it will often be the case that clinicians can have a high degree of

confidence that the tested level is above the infant's (un)aided behavioral threshold.the infant is perceiving the sound that elicited the cortical response.

Second, consider the case where no cortical response is present (i.e. $p \geq 0.05$). If the true sensation level of the sound were to be > 10 dB SL, the results of this experiment indicate that the most likely outcome (77 % probability, confidence interval range 60 % to 90 %) is that a cortical response would have been observed. If the sound truly is inaudiblebelow the infant's (un)aided behavioral threshold, then the statistical detection criterion adopted ($p < 0.05$) will ensure no response is detected 95 % of the time. If the true sensation level were to be within the range 0 to 10 dB SL, then the probability of a significant response being detected is intermediate; this experiment for example indicates that there is a $15/27 = 56$ % chance of a response being detected (sensation levels 0, 5, and 10 dB SL incorporated). When, in actual use, the true sensation level is unknown, these experimental results taken together indicate that the lack of a cortical response indicates a likelihood, but by no means a certainty, that the sensation level is 10 dB or less.

8.5 CAEP hardware and measurement parameters

8.5.1 Transducers

HEARLab ACA presents speech sound test signals in the free-field only. This is appropriate for the evaluation of hearing both pre- and post-fitting of hearing aids. Distances between the participant's head and the loudspeaker in the free-field have varied across studies from 7.6 cm (Brown, Klein, & Snydee, 1999), 20 cm (Kushnerenko et al., 2002), to 1 meter (Simos & Molfese, 1997). The angle between the head and the speaker is not always reported in studies, but when it is noted, it varies significantly (Kurtzberg, 1989; Kushnerenko et al., ibid). The use of a loudspeaker positioned at 90^o azimuth relative to the test ear (TE) has been reported (Brown et al., ibid) as has the use of two loudspeakers positioned at 45^o facing the right and left ears (Purdy et al., ibid). One study has reported the use of a loudspeaker positioned directly above the participant and equidistant to both ears (Simos et al., ibid). It can be concluded that while it is important to measure the stimulus intensity at the TE, the issues of angle to the speaker and distance from the participant are not critical to the recording of the cortical responses.

The HEARLab CTE module delivers stimuli by insert earphones and bone conduction (BC) only. Insert earphones offer a number of advantages over headphones that apply equally to evoked potential testing and standard audiometry. First, they offer increased accuracy in the estimation of threshold in the low frequencies because of reduced variability arising from air leaks around standard headphones (Gordon, Phillips, Helt, Konrad-Martin, & Fausti, 2005; Zwislocki et al., 1988). Second, the insertion depth that is required for positioning the device attenuates physiological noise in the ear and external ambient noise which makes the use of sound-treated test facilities less critical (Clemis, Ballad, & Killion, 1986; Gordon et al., ibid; Zwislocki et al., ibid)). Third, the potential for ear canal collapse in older adults, and hence false air conduction (AC) thresholds, is eliminated (Clemis et al., ibid; Gordon et al., ibid). Fourth, insert earphones maximize inter-aural attenuation and reduce the need for masking in the non test ear (NTE) which is particularly useful when significant asymmetric or conductive hearing loss exists (Clemis et al., ibid; Gordon et al., ibid; Killion & Villchur, 1989; Zwislocki et al., ibid). Finally, they provide increased comfort when worn for extended periods (Clemis et al., ibid; Gordon et al., ibid).

The recording of cortical responses to bone conducted tone-burst stimuli is not performed routinely but its application should not be considered any more problematic than in behavioural testing (Durrant & Hyre, 1993). For unmasked bone conducted responses, placement of the device on the electrode-free mastoid (see 3.1.2.2) should be satisfactory given that the head offers very little inter-aural attenuation to BC stimulation in adult subjects (Hall, 1992).

8.5.2 Speech stimuli

Three speech stimuli (/m/, /t/, /g/) are available through the ACA unit. They have been extensively used in cortical response projects at NAL (Dillon, Golding, Purdy, & Katsch, 2006; Golding, Dillon, Seymour, Purdy, & Katsch, 2006; Golding, Pearce, Seymour, Cooper & Ching, ibid) for the assessment of infants with normal hearing and those fitted with hearing aids. The duration of these stimuli have been determined based on experimental evidence gathered at NAL (Golding et al. 2006).

8.5.3 Polarity

Speech stimuli are presented with alternating polarity in the ACA unit. The selection of signal polarity is not critical to recording CAEPs (Hall, 2007; Hyde, 1997), but as the use of stimuli that alternate in polarity is known to be effective in reducing the contaminating effects of stimulus artifact upon the waveform (Hall, ibid; Hyde, ibid; Goldstein & Aldrich, 1999), it has been incorporated in this module. As the statistical analysis of the response waveform is based on that portion of the waveform occurring after the stimulus has finished, there is no chance of stimulus artifact affecting the statistical detection process, even were polarity alternation not to be used.

8.5.4 Repetition rates

Speech sound test signals are presented in the ACA unit with an inter stimulus interval (ISI) (i.e., the period between stimulus offset and the following stimulus onset) of 1125ms. In studies where adult-generated cortical responses are recorded, an ISI of 1 or 2 seconds has been reported as clinically satisfactory (Hyde, 1997; Stapells, 2002). Variations in the ISI with the speech stimuli /uh/, have been recently shown to impact on the components of the cortical response in children 3-12 years in a highly complex manner (Gilley, Sharma, Dorman, & Martin, 2005) but the impact of ISI change in infants has not been widely reported. In a NAL study using the original /m/ and /t/ stimuli, the stimulus duration was fixed at 79 ms but the ISI was varied from 750 ms to 1125 ms and 1500 ms. In infants, the amplitude of the cortical response increased significantly as the ISI increased from 750 to 1125 ms but not from 1125 ms to 1500 ms (Golding et al., 2006, ibid). As there was no clear advantage in using the 1500 ms rate and test time would be increased, the shorter 1125 ms ISI appears to be a satisfactory and appropriate interval.

The ISI for tone-burst stimuli within the CTE module is also 1125 ms. This is well within the recommended range of one to two per second (Abramovic, 1990) that optimizes the amplitude of the cortical response (Goldstein et al., 1999).

8.5.5 Tone burst characteristics

The tone-burst envelope comprises a rise and fall time of 10 ms each and a plateau of 30 ms. The rise and fall shape follows the cosine curve over 90° with an equivalent overall period of 40 ms. Variations to the rise/fall and the duration of tonal stimuli have complex

implications for the amplitude and latency of adult cortical responses. When the rise/fall is brief (e.g., 3 ms), an increase in response amplitude and a decrease in response latency might be expected as the duration of the stimulus plateau varies from 0 – 30 ms and up to 70 ms (Alain, Woods, & Covarrubias, 1997; Onishi & Davis, 1968). When the rise/fall is 5 ms, the amplitude of the cortical response is nearly constant as the duration is varied from 2 – 320 ms (Davis & Zerlin, 1965). Optimal responses are, however, recorded with rise/fall times and plateau times of greater than 10 ms (Onishi et al., ibid; Rothman, Davis, & Hay, 1970). The stimulus envelope offered in the CTE module is therefore selected to meet this requirement, but it is not long enough to overlap with the response.

8.5.6 Masking

Narrow-band noise is offered as the masking signal in the CTE module.

Narrow bands of noise centered at pure-tone test frequencies are routinely and effectively applied to the NTE in audiometry (Hall, 2007; Hyde, 1997) and are appropriate for cortical testing when tone burst stimuli are delivered via AC or BC (Goldstein et al., 1999). The level of masking applied to the NTE may follow normal audiometric rules (Reid & Thornton, 1983). This would involve unmasked evaluation of audibility for all frequencies of interest in both ears before re-evaluation (with masking applied to the NTE) for those frequencies where a cross-heard stimulus is possible. Given the increased inter-aural attenuation offered by insert earphones, masking to the NTE may not be needed for stimulus levels in the TE £ 70 dB HL as inter-aural attenuation for insert earphones may be as much as 60 dB (Hall, 2007). For stimulus presentation levels above this (or when stimulation is by BC), the CTE module offers a masking level range of +10 to -30 dB (relative to the stimulus presentation level). With an extreme stimulus presentation in the TE of 110 dB, the contralateral masking will be 80 dB or more, which may lead to over-masking in some cases.

8.5.7 Number of signal channels and electrodes

The ACA and CTE modules offer a single channel for signal detection.

For cortical response detection a single channel is quite satisfactory (Roger & Thornton, 2007). And given the practical challenges of attaching electrodes and maintaining placement during testing, HEARLab's single channel recording system is appropriate. In a recent NAL study where the validity of a statistical technique in the detection of cortical responses was evaluated, cortical responses from ten adult subjects were recorded to two speech stimuli presented at five sensation levels (relative to their auditory threshold). While recordings were made at three electrode sites; C3, Cz, C4, no discernable difference in response morphology could be observed across the three sites (Golding et al., 2009). As a result reporting was restricted to responses recorded using the single channel of Cz.

8.5.8 Electrode placement

For ACA and CTE modules, the examiner is advised to position the active electrode on the vertex (Cz*), the reference electrode on the earlobe (A1 or A2*) or on the mastoid (M1 or M2*), and the ground electrode on the forehead (FPz*).

For cortical response detection, placement of the active electrode at Cz or within two to three cm of the site ensures optimal amplitude of the cortical response in most cases (Hall, 2007). Based on measurements of the distribution of potentials across the scalp

(Sussman et al., 2008) and on theoretical considerations arising from the angle of inclination of the surface of the auditory cortex, positions forward of the vertex (such as FCz) may offer higher cortical response amplitudes. Even a forehead position is a feasible alternative to placement at the vertex but an undesirable increase in eye movement artifact will be evident in the recording (Hyde, 1994). In recent NAL studies, where the effect of lateral variations in electrode position on infant and adult cortical responses was specifically examined, the dominant adult N1 response was largest at Cz (compared with C3 and C4) (Purdy et al., 2006) while the dominant infant P1 was largest at C3 by 1 to 2 μV (Golding et al., 2006).

The use of mastoid or earlobe placement for the reference electrode is common (Goldstein et al., 1999; McPherson, 1996) but given the small surface area of an infant's earlobe, mastoid placement may be more practical in these cases. The detection of the cortical response is independent of the ear under stimulation and so it is not necessary to move the reference electrode from one mastoid to the other during testing (Stapells, 2002). Although many positions for the ground electrode are plausible, a forehead position is one of the easiest to achieve (Goldstein et al., ibid).

8.5.9 Display

The cumulative averaged cortical response is displayed in both the ACA and CTE modules. A shaded age-typical latency band for the first positive peak (mean P1 latency± 2 SD) is displayed for children, and shaded typical latency bands for P1, N1 and P2 is displayed for adults.

The cumulative average response is shown in the time domain with latency (measured in ms) displayed on the X-axis as a function of amplitude (measured in μV) on the Y-axis. The latency scale is fixed at - 200 to + 600 ms (although waveforms cease at 550 ms) while the amplitude scale defaults to -15 to +15 μV but it can be modified by the examiner (unlimited scale).

As cortical responses are particularly susceptible to changes in client state (Goldstein et al., 1999; Hall, 1992; Hyde, 1994; Stapells, 2002), the addition of a pre-stimulus baseline (-200 to 0 ms) is advantageous (Hall, 1992). The baseline period serves two purposes. First, if the waveforms are being evaluated visually (which is not necessary in the case of HearLab because of its internal statistical calculator) the baseline portion enables the size of fluctuations where there should not be any response to be compared to those in the region where a response might be expected. Second, the voltage averaged across the baseline period should be zero. Any non-zero value is therefore the effect of low-frequency noise from the head or the measurement system that has not been removed by averaging. This value is subtracted from the entire waveform, a process known as baseline correction.

As stated, the morphology of the major components of the cortical response change substantially with respect to the shape and latency over the first 14-16 years of life. The duration of the X-axis is therefore sufficient to accommodate these age-related changes to latency.

The age-appropriate latency band was derived from a NAL study (Golding et al., 2006). The latency results for P1 in 54 infants, aged 0.2 to 0.75 years were plotted together with adult latency values and data published by Sharma and colleagues in which the P1 latency for adult normal hearers and those with cochlear implants is reported (Sharma et al., 2002). The shaded band that is superimposed on the averaged display represents these findings.

The ACA and CTE modules also display an indicator of residual noise, which is based on the inter-epoch variability and the number of accepted epochs in each averaged stimulus-generated response. This indicator provides the examiner with desirable information on the likelihood of a response, if present, being detectable given the number of accepted epochs and electrical activity within the accumulated epochs.

The rms value of the residual noise that is superimposed on the averaged accepted epochs is calculated concurrent with the detection p-value (see 3.1.4.1) and the magnitude is shown as the HearLab "traffic light". The color "red" is used to denote a calculated rms residual noise voltage in the average waveform > 3.6 μV; "yellow" denotes 3.2 μV < residual noise rms value < 3.6 μV; and "green" denotes residual noise rms value < 3.2 μV.

The residual noise rms values were previously calculated for data collected from 14 babies with normal hearing listening to sounds at 10, 20 and 30 dB sensation level (Carter et al., 2010). Detectability of the cortical response was high whenever the residual noise was less than 3.4 μV, which provided the basis for the criterion adopted.

8.6 Statistical processing

ACA and CTE modules apply Hotelling's T2 (Flury & Riedwyl, 1988; Harris, 2001) for detection of cortical responses.

To achieve this, the sampling points for this averaged response are reduced to nine variables to form a "response" condition for further analysis. As the latency of key response components varies with age, the point of commencement and duration of the analysis period also varies. For infants 0 – 2 years, the analysis period commences at 101 ms post-stimulus onset with an end point at 550 ms; for 2 – 10 year olds, analysis commences at 76 ms (end point at 450 ms); for ages > 10 years, analysis commences at 51 ms (end point at 350 ms). With ten averaged responses per stimulus, Hotelling's T2 is applied to calculate the probability (p) that the mean value of any linear combination of the nine variables is significantly different from zero. The resulting p-value is presented numerically and also graphically using a color-code that is consistent with the cumulative average display. This value is continually refreshed with every increment of ten in averaged responses, until the stop-criteria for the test is reached.

Automated and machine scoring methods for detection of evoked responses is not new, but it has not been routinely applied in the detection of cortical responses. The application of Hotelling's T2 in cortical response detection has been recently reported using both adult- and infant-generated cortical responses (Golding et al., 2009; Carter et al., 2010).

8.7 Clinical performance of HEARLab system

Carter et al. (2010) have conducted a study which investigated the effectiveness of an automated statistic versus experienced examiners in detecting the presence of infant CAEPs when stimuli were present and reporting the absence of CAEPs when no stimuli were present. A repeated-measures design was used where infant-generated CAEPs were interpreted by examiners and an automated statistic. There were nine male and five female normal-hearing infants (mean age, 12 mo; SD, 3.4) who completed behavioral and electrophysiological testing using speech-based stimuli. In total, 87 infant CAEPs were recorded to three sensation levels, 10, 20 and 30 dB relative to the behavioral thresholds and to nonstimulus trials.

Three examiners were presented with these responses: (1) "in series," where waveforms were presented in order of decreasing stimulus presentation levels, and (2) "nonseries," where waveforms were randomized completely and presented as independent waveforms. The examiners were given no information about the stimulus levels and were asked to determine whether responses to auditory stimulation could be observed and their degree of certainty in making their decision. These expert examiners had 2, 3, and 8 years of experience with infant CAEPs, respectively. Data from the CAEP responses were also converted to multiple dependent variables and analyzed using Hotelling's T2. Results from both methods of response detection were analyzed using a repeated measures ANOVA (analysis of variance) and parameters of signal detection theory known as d-prime (d') and the area under the receiver operating characteristic (ROC) curve.

Results showed that as the stimulus level increased, the sensitivity index, d', increased for both methods of response detection, but neither reached the maximum possible d' value with a sensation level of 30 dB. The examiners with the greatest experience and Hotelling's T2 were equally sensitive in differentiating the CAEP from noise. It was concluded that Hotelling's T2 appears to detect CAEPs from normal hearing infants at a rate equal to that of an experienced examiner. A clinical instrument that applies Hotelling's T2 on-line, so that the likelihood of response detection can be assessed objectively, should be of particular benefit to the novice or less experienced examiner.

The detection performance for each speech sound (/m/ and /t/) by HEARLab and the three examiners is provided in Tables 8.7.1 and 8.7.2.

Table 8.7.1. Detection performance results for stimulus /m/.

/m/	Percent detected* and number fraction (with 95% confidence interval for HearLab)			
	30 dB SL	20 dB SL	10 dB SL	No Stimulus
HEARLab	82 (9/11) (53-97)	73 (8/11) (43-92)	27 (3/11) (8- 57)	0 (0/11) (0-19)
Examiner 1	82 (18/22)	68 (15/22)	36 (8/22)	5 (1/22)
Examiner 2	64 (14/22)	36 (8/22)	9 (2/22)	0 (0/22)
Examiner 3	50 (11/22)	36 (8/22)	45 (10/22)	27 (6/22)

Table 8.7.2. Performance results for stimulus /t/.

/t/	Percent detected* and number fraction (with 95% confidence interval for HearLab)			
	30 dB SL	20 dB SL	10 dB SL	No Stimulus
HEARLab	73 (8/11) (43-92)	36 (4/11) (14-65)	27 (3/11) (8-57)	0 (0/10) (0-19)
Examiner 1	86 (19/22)	36 (8/22)	27 (6/22)	0 (0/20)

Examiner 2	86 (19/22)	32 (7/22)	9 (2/22)	0 (0/20)
Examiner 3	64 (14/22)	45 (10/22)	23 (5/22)	10 (2/20)

*To calculate percent detected for examiners, examiner ratings of 4 or 5 are counted as "detected" and in series and non-series results are pooled.

Golding et al. (2009) compared the effectiveness of the automatic statistic with expert examiners in (1) detecting the presence of CAEPs when stimuli were present, and (2) reporting the absence of CAEPs when no stimuli were present.

CAEPs recorded from ten normal-hearing adults, using two speech-based stimuli, five stimulus presentation levels, and non-stimulus conditions, were given to four experienced examiners who were asked to determine if responses to auditory stimulation could be observed, and their degree of certainty in making their decision. The expert examiners had 7, 10+, 5, and 10+ years of experience with CAEP, respectively. These recordings were also converted to multiple dependent variables and Hotelling's T2 was applied to calculate the probability that the mean value of any linear combination of these variables was signifi cantly different from zero.

Results showed that Hotelling's T2 was equally sensitive to the best of individual experienced examiners in differentiating a CAEP from random noise. It is reasonable to assume that the difference in response detection for a novice examiner and Hotelling's T2 would be even greater.

The detection performance for each speech sound (/g/ and /t/) by HEARLab and the four examiners is provided in Tables 8.7.3 and 8.7.4.

Table 8.7.3. Performance results for stimulus /g/, 100 epochs.

/g/ 100 epochs	Percent detected*(and 95% confidence interval for HearLab)					
	Sensitivity					
	+30 dB SL	+20 dB SL	+10 dB SL	0 dB SL	-10 dB SL	No Stimulus
HEARLab (N=10)	100 (81-100)	100 (81-100)	100 (81-100)	80 (50-96)	10 (1-39)	10 (1-39)
Examiner 1 (N=20)	95	95	80	30	0	0
Examiner 2 (N=20)	100	95	75	40	5	5
Examiner 3 (N=20)	100	100	90	45	0	5
Examiner 4 (N=20)	100	100	100	60	5	5

Table 8.7.4. Performance results for stimulus /t/, 100 epochs.

/t/100 epochs	Percent detected*(and 95% confidence interval for HearLab)					
	Sensitivity					
	+30 dB SL	+20 dB SL	+10 dB SL	0 dB SL	-10 dB SL	No Stimulus
HEARLab (N=10)	100 (81-100)	100 (81-100)	100 (81-100)	50 (22-78)	0 (0-19)	0 (0-19)
Examiner 1 (N=20)	100	100	80	20	0	5
Examiner 2 (N=20)	100	100	90	35	0	5
Examiner 3 (N=20)	100	100	80	40	10	0
Examiner 4 (N=20)	100	100	90	45	0	0

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Practical Aspects of CAEP Testing with Infants

The HEARLab system has been designed to make objective audiological assessment as easy and efficient as possible. However, testing young children, regardless of the hardware and software employed, presents practical challenges.

The application of CAEPs to a pediatric population may be relatively new to mainstream clinical practice, however, the general techniques and strategies used in other areas of pediatric audiology are still highly relevant. Experienced clinicians will be well aware of how to best manage the test environment, and will have developed many of their own solutions to overcoming the issues that inevitably arise when working with infants.

The clinical validation trials of the new HEARLab system involved repeated CAEP measures, conducted in a controlled and systematic way. This provided a valuable opportunity to investigate different approaches and test techniques, and to consider their relative merits, without the usual restrictions of a routine clinical assessment appointment, in which a diagnostic outcome must be achieved within a limited time frame.

Some general suggestions, based on observations made during the study, are summarized in this Appendix. It is hoped that this information may provide useful guidance, particularly for clinicians with less experience in pediatric audiology, or those who are new to using electrophysiological assessment techniques with young children.

Before the appointment

- Prior to the appointment, provide parents/care giver with information (written and verbal) about the procedure. This will reduce the time spent in explanation at the assessment.
- When arranging the appointment, ask about the child's routines. Try to book the test at a time of day when the child is likely to be in a "good" mood, and less likely to be overtired and irritable. Allow plenty of time so that appointment is not rushed, and it is possible to take breaks if needed.
- Check whether the parent/care giver intends to bring sibling/s to the appointment. If it is necessary for siblings to attend, make sure there will be suitable activities/ supervision away from the test room. The parent should be free to focus their attention on the child having the test.
- Ask the parent/care giver to bring food, drinks, or dummies ("pacifiers") for the child, to the appointment. Some favorite toys, that are suitable as quiet distracters, can also be useful in making the child feel more secure in the test environment. DVDs that the child enjoys can also provide familiarity and useful distraction.
- Suggest that the child be dressed for the assessment in layers of clothing that can be easily removed. Electrode contact can be comprised if the child becomes overheated and "sweaty" and it may be necessary to remove clothing to cool them down. It is better not to have to pull clothes over the child's head once they are "wired up".

- Ask parents/care giver to ring and postpone the appointment if their child is unwell, particularly if the child has a temperature. A restless and irritable state is not conducive to quality recordings.
- Call the parent/care giver to confirm the appointment the day before, and take the opportunity to check whether they have any questions or concerns they would like to discuss.

Test environment

- Make the test environment "child friendly'". For example, decorate the test booth and surrounding areas using items such as mobiles, displays of soft toys (out of the child's reach), and fabric motifs. Avoid hard reflective objects that will cause sound reflections. Minimize technical "clutter". Keep wires out of view and laboratory supplies in drawers. Children, particularly if they have undergone medical treatment or hospitalization in the past, may associate such items with unpleasant procedures.
- Keep the test area clean and tidy. A plastic backed 'Draped' sheet (available from medical suppliers) is a useful surface for arranging preparation materials, and for wrapping used electrodes, cotton tips etc. afterwards for disposal.
- Provide a chair that is as large enough for the child to sit comfortably, either on their parent's lap or beside them, during testing. Some children become irritable if they feel overly restrained or restricted in their movements. Where possible, try to let them settle into a position which they prefer. A recliner chair works well as it can be used for adult testing as well.
- Use washable covers on the chair (eg, bath toweling) and change between assessments to maintain hygiene. This makes "dribbles" and food spills easier to contain and reduces parents inclination to perform immediate "clean ups", which can disrupt the testing. Have tissues or baby wipes at hand if needed.
- Have a container on hand to collect items that require cleaning, according to infection control guidelines (eg, toys that have been in the child's mouth).
- Some younger infants may be comfortable in a rocker/"Fraser chair", but don't rock the baby during recordings. "Bounces" can be evident in recordings and rocking can make a child sleepy.
- Fluorescent lighting can cause problems of electrical interference. Incandescent lighting should be used in preference. As well as providing a technical advantage, incandescent lamps can create a pleasant, relaxed ambience for children and parents. Novelty lamps (eg, artificial fish tanks, "lava" lamps), as well as providing illumination, can provide the child with visual distraction.
- It is important that the tester is able to monitor the test environment and the baby's state throughout the test. A strategically placed video camera can be extremely helpful if the arrangement of the test booth makes it difficult to maintain a clear view. A video camera that works well in low light is recommended.
- Where the tester is in a separate observation room, an audio monitor is essential in monitoring the ambient noise level in the test environment, to ensure consistent stimulus delivery, and is also useful in communicating with the distracter.

Preparation for testing

- Children generally have a short attention span, and their mood and state can change quickly. Have all test equipment switched on, checked and calibrated before the child arrives. Have the recording system software open and ready on the impedance check screen to avoid unnecessary delays.
- If testing is with hearing aids on, change the batteries and check the devices on arrival. Having another staff member do this while you are interviewing the parent, this will minimize delay in commencing testing.
- Ensure that the parent understands what is involved in the test. The child is more likely to be relaxed and cooperative during the assessment if their parent is confident and relaxed about what is happening.
- Make the parent comfortable. Providing a hot drink or glass of water can help put parents at ease. It is a good idea to have a safe place to put a drink beside a parent so that it cannot be knocked onto baby or electrical equipment.
- Ensure the parent feels in control of the situation. Seek their advice about the child's preferences, and the best strategies for preparing them for testing. Respect their opinion and follow their suggestions.
- Try to build some rapport with the child. A little physical interaction with the child while you are interviewing the parent (eg, patting or stroking their arm or head) can be useful in gauging how they will react to the preparation for electrode sites, and may possibly help the child accept it more readily.
- Make sure the child's physical needs (eg, nappy diaper changing) are attended to before starting preparation for the electrode placement.
- Have any items that might be needed (eg, bottles, food, toys) close at hand, in order to minimize noise and disruption during testing. Check with parents to see if bottles need warming or food needs preparation before you start.
- Attempt otoscopy and tympanometry first if indicated, but don't persevere if it causes the child to become too active or distressed.
- Ask parents to switch off mobile 'phones or pagers as these may cause distraction to the child if they ring during testing, and may also be a potential source of electrical interference.

Preparation of electrode sites

- Attaching the electrodes is potentially the most challenging part of the test procedure. Approach the preparation confidently but not too forcefully. Smile, and talk to the child reassuringly.
- Start the preparation in a position where the child is comfortable and not overly restrained. For example, try starting while an older infant is playing on the floor, or at a child's table and chair.
- Try not to physically "stand over" the child while doing skin preparation. Working from behind the child may be a good option. For your own health and safety, try to maintain a posture that is ergonomic and doesn't place strain on your back or neck. Sitting on the floor beside baby whilst chatting to Mom or Dad and gently rubbing the skin can be a very non-threatening way to get the skin prepared.
- Electrode sites are generally prepared by abrading with a cotton applicator

'bud' and a medical gel intended for the purpose. Rub firmly and vigorously enough to cause a slight redness on the skin surface, but not so hard that the child becomes obviously distressed by the sensation. Rubbing gently, but firmly, back and forth works better than "dabbing" at the skin. Rub on the back of Mom or Dad's hand first so they know what it feels like.

- Work as quickly as possible and minimize the number of physical contacts with the child. Don't fuss or "overdo" it, but be mindful that it is better to prepare skin thoroughly than to have to repeat the whole process.
- If the child needs reassurance about the preparation, modeling the procedure (eg, by rubbing the forehead of the parent or a doll with a cotton bud, and sticking on an electrode) can be helpful. Try letting an older child have a "turn" at putting an electrode on a toy or on their parent.
- Some children will be reassured by watching the preparation in a mirror, but this may make others more apprehensive.
- Television can be a good distraction during electrode placement. Use a range of children's DVDs with lots of color and movement. If the child becomes interested, the DVD can be left playing (with the sound muted) when testing starts. This is the time to use your noisy, fun toys, before the real testing begins! Make sure you put these out of sight before you start.
- Wherever possible have a trained distracter (in addition to the parent), to interact with the child during electrode placement, as well as during testing. Toys that involve some fine motor manipulation (eg, block stacking, button pressing) can help keep hands away from the electrode sites, and at this stage toys that make a noise are suitable.
- Cleaning skin with an isopropyl alcohol prep swab after abrading is sometimes recommended, and may improve contact, but it can make the electrode stick very firmly and make it difficult to remove. It can also feel "stingy" – try it on yourself if you don't believe this! Therefore, alcohol pPreparation with an alcohol wipe is not needed and is not recommended for the delicate skin of infants.

Optimizing and maintaining electrode contact

- Use a liberal amount of electrode paste under the vertex electrode even if a disposable electrode, that already contains conductive gel, is used.
- If using disposable electrodes, a spot of double sided tape (the type used for retaining hearing aids) on the underside of the plastic tab of the electrode stud, can give a firmer hold, particularly for mastoid or forehead sites (ie, where the skin is free of hair).
- A headband is very helpful in keeping the electrodes in place, particularly at the vertex, but some children are less accepting of wearing a headband than others.
- To make wearing a headband more appealing to the child, choose colorful, soft and stretchy materials. Give older children a choice of colors or designs (eg, have a selection of different motifs sewn on a selection of headbands). Having a choice of "girls" or '"boys'" styles can be important to the child, and sometimes also to the parent. Use fabrics that are easy to wash and dry after use.
- Dividing the top of the headband before use (by cutting a slit a few inches long across its centre) allows a section of fabric to be stretched forward to hold the forehead electrode in place.

- Passing the leads under the headband can help reduce pulling and strain on the electrode site during the test.
- Elastic bandage, particularly of material that allows the ends to adhere without pins or tape (eg, "peg" bandage), can be a reasonable alternative, but tends to be more "fiddly" to put on than a headband. If an inexpensive type is chosen it can also be disposed of after use which can be an advantage.
- Micropore tape (either on its own or with a headband) is appropriate for keeping re-usable type electrodes attached.
- Once the electrodes are attached, try to drape the leads behind the child, avoiding contact with the child's face or neck. If the child can feel them, they will be more inclined to pull at them. Try to keep the leads away from clothing (eg, don't let them become tangled in bibs or collars).
- Loosely taping the leads to the back of the child's clothing (using micropore tape) may be helpful, but ensure they are not taped so tightly that the electrode leads are pulled off the head if the child suddenly leans forward.
- Make sure that if the parent is holding the child, that the electrode leads are not cramped or pulled under the parent's arm. Try directing the leads up and over the parent's shoulder
- Avoid the child leaning back onto the electrode leads, or making sudden large movements, such as lunging forward. Strategic use of distraction toys can help in this respect.
- If the child starts to touch the leads or electrodes don't over-react (eg, grab suddenly at the child's hands). In preference, try to distract the child by offering them an alternative item to play with.
- Once the electrodes are in place, avoid touching them unless really necessary (ie, they are obviously slipping/becoming unstuck). Drawing child's attention to them will often result in renewed efforts to remove them.
- Don't let the child overheat. This can result in electrodes lifting and the reject rate increasing. If the child gets very restless it can be better to suspend testing than let it proceed until they are "hot and bothered".

Distraction techniques

- The distracter is best seated in a comfortable position at, or below, the child's eye level. Care must be taken to maintain an appropriate position in relation to the speaker if the stimulus is presented free-field.
- Have a wide selection of age appropriate toys that are not too noisy. Keep toys and other distraction aids in easy reach, to minimize noise and disruption as the test proceeds. Choose toys that can be cleaned according to infection control procedures. Toys that can't be cleaned (eg, soft toys) should be kept out of the child's reach.
- For very young infants, the main aim of distraction is to keep them alert and awake (they do not have the motor skills to pull at the leads or electrodes). Mobiles, hand and finger puppets are all useful items. Visual novelties (eg, toys with lights and motion) can be excellent. Some mechanized toys are too noisy to use while the testing is in progress, but can be good to use during breaks, in order to regain a child's interest and increase alertness.
- Toys that are used for VROA distraction are generally suitable for children in

the 7- 24 month age group. Examples include; stacking plastic rings or cups, farm animals, large counting and threading beads, puzzles, colorful teething rings and so on. Items that keep hands occupied are ideal for children old enough to manage them.

- For younger children or those who are not developmentally ready to "play" with items, toys with texture (eg, spiky plastic balls, plastic animals etc) can be interesting for the child to touch or mouth (make sure you put them in the "washing" container after use).
- Action toys (eg, water-wheels, small spinning tops, "pecking" birds, '"wobbly" animals, clear plastic balls that contain moving toys) can be useful as long as they are not too noisy. If children are allowed to hold the items they should not contain small parts that may be a choking hazard, and they must be easy to clean. Watch that water-filled toys don't leak.
- For older infants (around 24 months and over) try coloring-in books with big colorful crayons, play-dough (if past eating it, or well supervised), paper with stickers or self-inking stamps.
- Books can be good for children of all ages. Heavy cardboard books of various shapes, or with flaps/pop-up features, can provide "hands on" activity. Books made of plastic (ie, intended for bath time) can be ideal for very young children as they are easy to clean if mouthed.
- Almost every child enjoys watching bubbles being blown. The small bottles used for parties are inexpensive and easy to use. Avoid "sticky" bubbles that are designed not to burst. They tend to leave messy residue in the test environment.
- Eating and drinking are excellent distracters. Good choices include baby bottles or infant sipping cups, and soft foods such as banana, custard, fruit gel, or sultanas. Avoid hard foods (eg, crunchy crackers) or large pieces of food of that require a lot of chewing, as the resulting noise and jaw movements can affect recordings.
- Breastfeeding is good for calming infants, but often can induce sleep. If the baby must feed during the assessment, watch very carefully and rouse the child gently if they begin to doze off, or appear their eyes start to appear "unfocussed". Be prepared to pause testing if the child's state becomes inappropriate. Sometimes a short break to have a feed can gibe baby a boost to keep them going for a bit more testing.
- Avoid distraction activities that are too stimulating or that encourage increased vocalization, for example, physically vigorous play, or games/gestures that encourage the child to answer questions or name objects. Parents may sometimes need some guidance about activities that are inappropriate in this respect.
- If the child is content and quiet it can be best for the distracter to sit quietly or withdraw and leave them to their own devices. If the child is unsettled sometimes it can help for the distracter to get right out of their view and let the parent try to calm themsettle the child before proceeding.
- Try to end the test on a '"happy note", rather than persisting until the child (and potentially the parent) is distressed. This is especially important if the child will have to attend on another occasion.

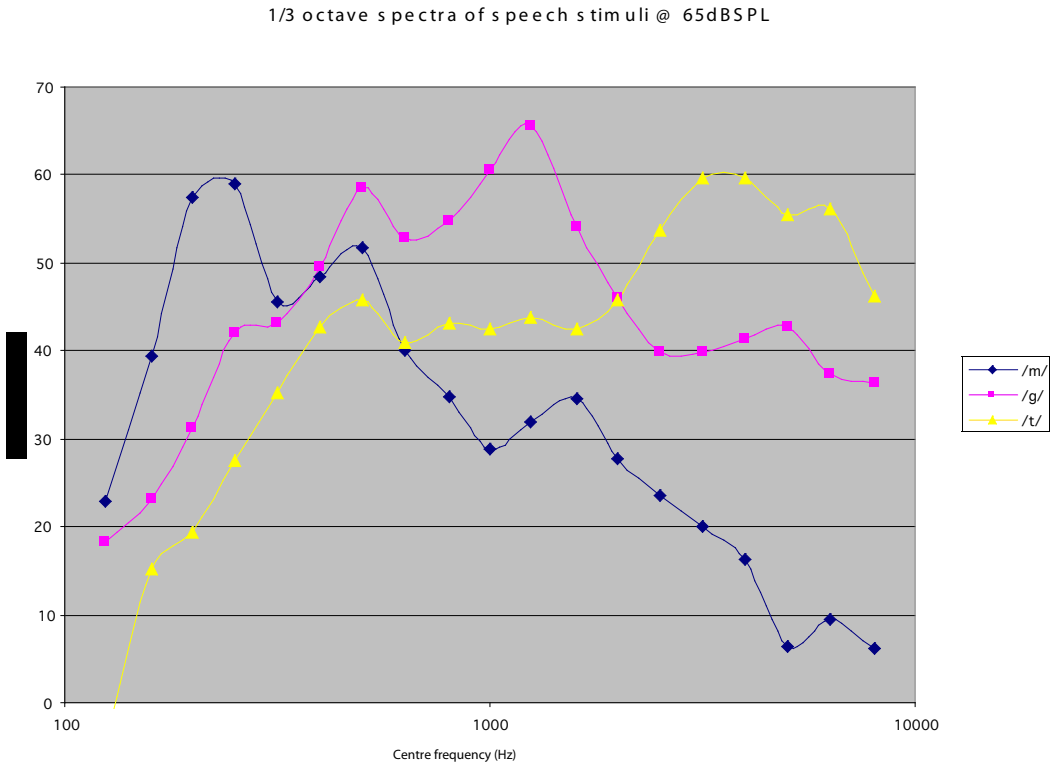
Ambient Noise Conditions—HEARLab™ ACA

Cortical Tone Evaluation (CTE)

To obtain a reliable measure of hearing ability, the ambient acoustic noise levels need to be sufficiently low relative to the levels of acoustic stimuli employed in tests. While Electrophysiological test methods are not included in the relevant international standard, ISO8253-1, the requirements it lays down on maximum permissible ambient sound pressure levels is recommended for CTE when either insert earphones or bone conductor is employed.

Aided Cortical Assessment (ACA)

ACA employs three speech sounds /m/, /g/ and /t/ as acoustic stimuli. These stimuli have dominant energy in the low, middle and high frequency bands respectively.



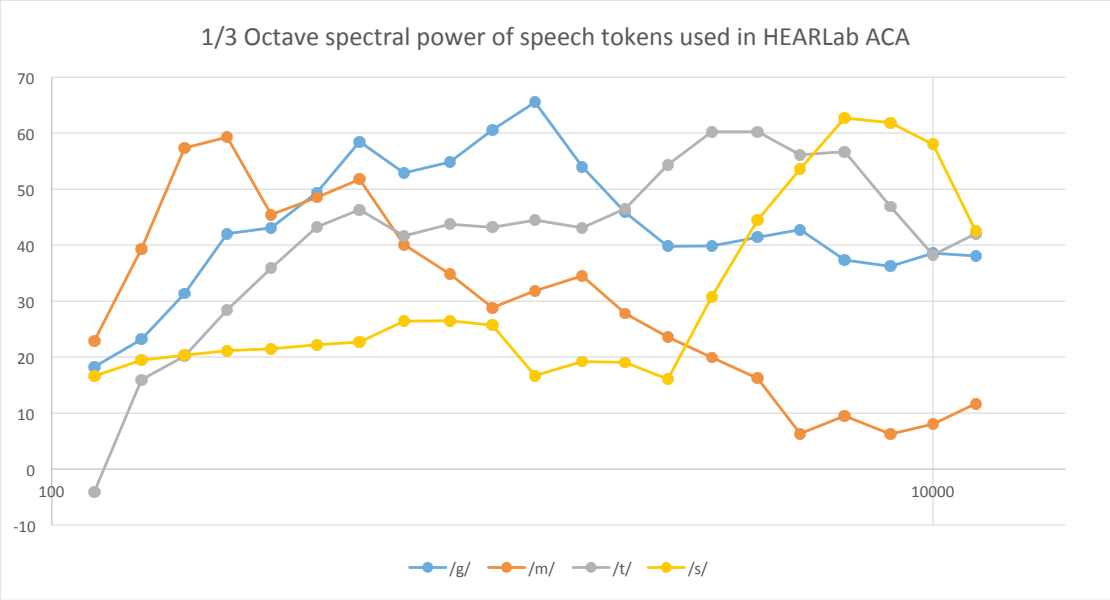
With the ACA procedure, the speech sounds are presented at default supra-threshold level of 65dBSPL. It is recommended that the 1/3 octave ambient noise levels be below 35dBSPL.

HEARLab™ ACA tools

HEARLab™ ACA includes a tool for automated measurement of ambient noise. The results are displayed in 1/3 octave band levels. For CTE applications, the software can also display the ambient noise limits for either bone conductor or insert earphone against dBHL. Refer section on Utilities 3.10.3

1/3 Octave spectral power of speech tokens used in HEARLab ACA
Normalized to 65dBSPL impulse power

Freqency	/g/ G20ms.WAV	/m/ M30ms.WA	/t/ T30ms.WAV	/s/ s50ms.wav
125	18.27905385	22.93818333	-4.029531157	16.64899529
160	23.22024893	39.37634735	15.95267551	19.50413013
200	31.35024415	57.37404691	20.19278027	20.39575191
250	42.06382607	59.2904683	28.43410632	21.18625524
315	43.12508765	45.4573859	35.87671239	21.47895814
400	49.46424223	48.57268986	43.30961348	22.23683513
500	58.51532404	51.79572281	46.35206418	22.71789963
630	52.93131129	40.12536686	41.64400042	26.4437416
800	54.8559231	34.87998734	43.75118827	26.49659907
1000	60.63371152	28.84574988	43.17083792	25.71162824
1250	65.58244677	31.89081449	44.45915934	16.7090715
1600	54.08522559	34.52482613	43.13218105	19.21956701
2000	45.90165983	27.83850341	46.4888832	19.02746306
2500	39.82115353	23.60033775	54.33412735	16.02696568
3150	39.84122688	19.9726968	60.31072113	30.82602326
4000	41.40787154	16.22340289	60.24966389	44.50181292
5000	42.79735888	6.334432301	56.18829019	53.6759414
6300	37.37300395	9.487538157	56.72706784	62.69649273
8000	36.25793523	6.238143852	46.91124093	61.86975094
10000	38.58452741	8.018147226	38.25629157	58.0431373
12500	38.11949774	11.72694091	42.09788633	42.5086308
Length msec	20.861678	30.04535147	30.29478458	50
Total Impulse power	65	65	65	65



Sources of Interference—HEARLab™

HEARLab used in evoked potential recording involves detection and analysis of signals of a few microvolts or lower in the frequency range of near DC to 5kHz. The following notes are intended to assist in reducing electrical interference that may affect recordings.

- **Magnetic field related to power supply:** Reduce pick up from transformers and inductor motors by minimising areas enclosed by the connector cables. Loosely 'braiding' the electrode connector cables together is often practical.
- **Electrostatic field related to power supply:** Unshielded fluorescent tubes and lamps and cables carrying power are sources of interference. This can be reduced with distance and shielding
- **Magnetic induction loops:** Some facilities are equipped with induction loops to transmit audio signals to hearing aids. They may need to be switched off if the interference is serious.
- **HF interference:** Interference from radios, mobile phones, local communication systems, TV broadcasting if serious may require shielding. Similarly medical equipment in proximity such as short wave diathermy can be the source of interference.

Static and movement: Movement of electrode cables within a static field can induce interference.

Technical Specifications—HEARLab™ ACA

HEARLab™ ACA device consists of a hardware platform (HEARLab™) and a software platform that work together to perform acoustically evoked cortical response measurements.

Hardware platform

Computer

Physical configuration	Standalone desktop base unit
Base unit dimensions	H, W, D : 4.5”, 15.7”, 13.9”: 11.4cm, 39.9cm, 35.3cm
Base unit eight	10.4 kg
Display	Standalone 17” LCD monitor
Keyboard	Standard 104-key PC keyboard
Mouse	Standard optical mouse

Electronics for acoustic presentation & monitoring

Physical configuration	Standalone Stimulus Controller (SC) box
SC dimensions	H, W, D: 4.7”, 12.6”, 11.5”: 12cm, 32cm, 29cm
SC weight	2.7kg
Sound Field Speaker	8 Ohms 5 Watts
Speaker dimension	H, W, D: 5.7”, 5.3”, 3.2”: 14.5cm, 13.5cm, 8.0cm
Insert earphones	ER3A 50 Ohms Left and Right
Bone vibrator	B71 Bone oscillator 50 Ohms
Monitoring microphone	0.55” diameter, 1.0” length

Electrode interface

Physical configuration	Standalone Electrode Processor (EP) box
EP dimensions	H, W, D: 2.2”, 4.2”, 9.0”: 5.5cm, 10.5cm, 23cm
EP weight	0.5kg
Electrode cables	60” (150cm) cable with amplifier integrated in connector button
Signal cable	1, yellow
Reference	1, blue
Ground	1, black
Electronic amplification	Analogue differential amplification of 1210 times
Low pass filter	Analogue, 12 dB/octave from 4kHz

High pass filter	Analogue, 6dB/octave below 0.3 Hz

Software platform

Operating system	Windows XP
Data management	Embedded MySQL

HEARLab™ ACA Software

Hearing tests available	Aided Cortical Assessment (ACA)
	Cortical Tone Evaluation (CTE)
Utilities	Check electrode impedance
	Quick check stimulus presentation
	Monitor ambient noise level in 1/3 octave spectrum

Acoustic stimulation -ACA

Stimuli type	Speech sounds extracted from running speech
Duration	/m/ 30mS
	/g/ 20mS
	/t/ 30mS
Repetition rate	1125mS
Number of stimulus	User select
Polarity	Alternating
Levels	55 or 65 or 75 dB SPL* user selectable
Transducer	Free field loudspeaker
Masking	Nil, non target ear may be blocked with earplugs

Acoustic Stimulation - CTE

Stimuli type	Short duration pure tone burst
Burst duration	40 mS
Rise time	10 mS
Fall time	10 mS
Tone frequencies	500, 1k, 2k, 3k, 4k Hz
Repetition rate	1125 mS
Number of stimulus	User select
Polarity	Alternating
Transducer	Bone vibration: B71 or
	Insert earphones: EARTone 3A
Levels - bone	0 – 70 dB HL, 1k – 4k Hz, 5 dB steps
	0 - 60 dB HL, 500 Hz
Levels – earphones	0 – 110 dB HL, 5 dB step size
Masking signal	Narrow band noise, insert phones only
Masking levels	0dB to -40dB user selectable relative to test level

Response Acquisition: ACA & CTE

Recording channels	2; response waveform, stimulus waveform
Time window	-200mS to +700mS relative stimulus start
Sampling rate	1000 Hz
A/D resolution	16 bits
Number of epochs	User selectable and interruptible
Signal to noise indicator	A red or yellow or green dot indicating good or satisfactory or poor strength of signal relative to overall level of noise
User controls on testing	Start, pause, stop and volume of acoustic monitoring
Other test status	Test level, number of epochs accepted or rejected, time elapsed and latest P values

Evoked cortical response processing

Latency	Time marking responses to stimuli: +/- 5mS
Amplitude	Response voltage: +/- 0.5μV
Response extraction	Averaging of responses time locked to stimuli
Response detection	Hotellings-t2 statistic, probability that the trace observed was caused the subject detecting the stimulus
Response differentiation	MANOVA statistic, probability that responses to the different speech sounds are different from each other, ACA only
Signal and noise quality	Displays status on the level of residual noise

Test results screen

Grand averages	Waveform(s) of final averaged cortical response(s)
Stacked traces	For CTE only. Waveforms of final average responses to the same tone burst frequency presented at different levels
Detection statistical analysis	Final P values and their history
Difference statistical analysis	Final P values and their history, ACA only
Summary of test conditions	Ear tested, aided or unaided, electrode condition, stimulus, masking, transducer, test duration and number of accepted epochs.
Comment	Space for user to add comments (recording keeping)

Test records

Test information	All information in the test results screen
Subject information	Name and test of birth
User controls	Store, recall, selection of records

Information displayed during response acquisition

EEG	Trace showing the most recent 9 epochs

Latest response	Waveform of the latest epoch
Averaged responses	Waveform(s) of time locked cumulative average(s) of response(s)
Detection statistics	Trace(s) of P value(s) resulting from detection statistical analysis
Differentiation statistics	Trace(s) of P value(s) resulting from MANOVA, ACA only
Signal to noise indicator	A red or yellow or green dot indicating good or satisfactory or poor strength of signal relative to overall level of acquired noise
Other test status	Test level, number of epochs accepted or rejected, time elapsed and latest P values

User test controls during response acquisition

Soft buttons	Start, pause and stop and volume of acoustic monitoring
Volume control	Vary the monitoring level of acoustics in the test space

Environmental

Operating temperature	15 to 30 degrees C (60 to 85 degrees F)
Operating humidity	20% to 80% (non-condensing)
Permissible ambient SPL, CTE	In accordance with ISO 8253-1
Permissible ambient SPL, ACA	< 30dBSPL, 1/3 octave spectrum, 200 Hz to 6300 Hz (measureable with software tool provided)
EMC specifications	Radiated and conducted emissions CISPR11
	Electrostatic Discharge Immunity: IEC61000-4-2
	Radiated RF Immunity: IEC 61000-4-3
	Fast Transient/Burst Immunity: IEC 61000-4-4
	Surge Immunity: IEC 61000-4-5

Power supply

AC input voltage range	100~240Vac
AC input frequency	47~63Hz
AC input current	8.0/4.0A (PC 5.0 + LCD 1.2 + SC 1.35) ???

Safety

Type of protection	Class 1
Degree of protection	Type BF
Mode of operation	Continuous

List of Device Hardware Components—HEARLab™

Tentative list of device components

Component Identification	Additional identification	Qty
PC desktop base unit†	?HEARLab H1000	1
Mouse	-	1
Keyboard	-	1
Video Display Unit	-	1
Stimulus Controller†	HEARLab H1000	1
Electrode Processor†	HEARLab H1000	1
NAL Ground Electrode Connector†	Black	1
NAL Reference Electrode Connector†	Blue	1
NAL Active Electrode Connector†	Yellow	1
Register pad		1
Control Microphone†*	?	1
Free Field Loudspeaker*	Frye Electronics, Inc	1
Insert Phone Left*	?	1
Insert Phone Right*	?	1
Bone conductor*	?	1
SRU-EPU Cable	?	1
FF Loudspeaker Cable	?	1
USB cable†		1
Mic Cable (S-Video cable) 12 ft		1
IEC AC input power cord		3
User Manual		1
Electrode sensor pads	Ambu Blue Sensor	25
Desktop Loudspeaker stand		1

Optional components

Component	Purpose
Monitor Speaker	For user to hear sound in the test room (when the user is a separate room)
Speech Microphone	For user to communicate with an distracter/ assistant in the test room (when the user is a separate room)

Distracter Headphones	For user to communicate with an distracter/ assistant in the test room (when the user is a separate room)
Loudspeaker stand, floor	For mounting free field loudspeaker
High power amplifier and loudspeaker	For set ups where the loudspeaker and subject test position is further apart
DVD player and TV	For distracting the subject by playing silent movies. Choose components that gives minimal amount of acoustic noise

Distraction Techniques for Testing Adults

To keep adult subjects relaxed and alert during the assessment, playing a silent movie is recommended. Some DVD players make too much noise, therefore it is important to choose one that is quiet. Locate the display, such as an LCD TV, more or less is in line with the loudspeaker so that the subject will be facing the test loudspeaker.

For some subjects reading may also be a good alternative to watching a silent movie.

Quick Start Guide to HEARLab™ ACA Software

Before opening the HEARLab™ ACA software application, ensure the following:

1. The device components are correctly connected
2. The device is turned on
3. Allow time after device switch-on before opening the application

After opening the application, take care to:

1. Not disconnect the SC from the PC
2. Not disconnect the EP from the SC
3. Not switch off the device before closing the application

To ensure accuracy of stimuli presentation:

1. Ensure all transducer calibrations are up to date
2. Perform a quick stimuli presentation level check before the client arrives

Pointers to training for use of the HEARLab device

A HEARLab training module in the framework of HEARNet (a public initiative from the HEARing CRC, Australia) has been developed and can be found on:

https://www.hearnetlearning.org.au

This module demonstrates the clinical application of electrophysiology knowledge for audiological assessment using the **HEARLab** device for Aided Cortical Assessment and Cortical Threshold Estimation.

The module is divided up into four parts:

1. Part 1: Introducing HEARLab
2. Part 2: HEARLab Operation: testing infants
3. Part 3: HEARLab Operation: testing adults
4. Part 4: Evaluation Survey

These training modules contain a Flash presentation, a voice-over, and pre-/post-training multiple choice questions to assess training efficiency. In Australia, professional audiologists can earn accrediation points when completing this module successfully.

This module is intended for healthcare professionals:

- Audiologists
- ENT specialists
- Hearing aid fitters
- Audiological diagnosticians
- Electrophysiologists
- Supervised audiology and hearing technology students.

In addition there is a dedicated HEARLab website to provide advice to the professional, accessible on ***http://hearlab.nal.gov.au***/ which contains

- a general introduction
- a HEARLab brochure
- the most recent HEARLab manual
- a video showing hints and tips when testing infants with HEARLab
- a video with a live feed of the HEARLab screen while recording an infant
- a textual list with hints and tips when testing infants involving appointment management, the test environment, preparation for testing, optimizing electrode contact, distraction techniques
- HEARLab publications and presentations
- current HEARLab research

- a training presentation
- Australian media coverage
- the HEARLab forum monitored by an administrator from NAL
- an FAQ with 10 different topics.

Glossary

A

ACA	Acronym for Aided Cortical Assessment. See Aided Cortical Assessment
Aided Cortical Assessment	One of the two hearing assessment protocols included in the HEARLab™ ACA software. The protocol involves presenting speech tokens /m/, /t/, and /g/ at conversational levels and measuring the cortical auditory-evoked responses to such stimuli. A present cortical response represents that the stimulus can be detected by the listener at the cortical level.
Assessment	A test defined by the hearing assessment protocol, test ear, and the stimuli presentation pathway. Each assessment is comprised of one or more runs. See Run

C

CAEP	Acronym for cortical auditory-evoked potentials. See Cortical Auditory-Evoked Potentials
Cortical Auditory Evoked Potentials	Brain responses to auditory stimuli measured at the cortical level (scalp).
Cortical Tone Evaluation	One of the two hearing assessment protocol included in the HEARLab™ ACA software. The protocol involves presenting pure tone burst stimuli at various hearing levels to estimate a client's hearing thresholds at the cortical level.
CTE	Acronym for cortical tone evaluation. See Cortical Tone Evaluation
Cumulative Average	Non-weighted average of all accepted cortical responses to a stimulus up to the current accepted response.

D

Detection P	The p value that represents the probability that the response to a stimulus is significantly different to random noise. A detection p value < 0.05 represents a significant response, i.e. the stimulus can be detected. See p Value

Difference P	The p value that represents the probability that two responses to two different stimuli are significantly different to each other. A difference p value < 0.05 represents a significant different, i.e. the two responses are different, and may be used as an indication that the brain was responding differently to the different stimuli. Difference P will start when responses to both stimuli are detected to be significant. See p Value
Distracter	A person or device or object that is used to keep the patient who is undergoing cortical tests quiet, engaged and awake.

E

EEG	Acronym for electroencephalogram. See Electroencephalogram.
EP	Acronym for electrode processor. See Electrode Processor.
Electrode Processor	The hardware unit to which electrodes are connected.
Epoch	A single presentation of a cortical test signal.

P

p Value	A probability value used in statistical analysis for indication of statistical significance. In HEARLab™, a very low p value is an indication that the probability is high of there being a relationship between the signals presented during the epochs and the averaged data presented on the analysis screen.

R

Residual Noise Level	A calculated value that indicates the quality of the cortical response recording in relation to the noise level of the signal. A residual noise level value ≤ 0.32 (represented by a red color) indicates a good quality recording; a value≤ 0.36 (represented by a yellow color) indicates a mediocre quality recording; and a value > 0.36 (represented by a red color) indicates a poor quality recording. Noise in the recorded responses can affect the reliability of the statistical analysis results, thus higher the residual noise level, less reliable the resulting statistical analysis.
Run	A single test within an assessment, defined by the stimuli presented and the level at which the stimuli are presented.